Fusion Pharmaceuticals Announces Second Quarter 2020 Financial Results And Business Update

- Following Fusion's June 2020 initial public offering, cash runway extended into 2024

HAMILTON, ON and BOSTON, Aug. 11, 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 second quarter ended June 30, 2020 and provided an update on clinical and corporate developments.

"By developing targeted alpha therapies (TATs), Fusion is taking a precision medicine approach to radiation therapy," said Chief Executive Officer John Valliant, Ph.D. "In addition to our lead program, FPI-1434, which is currently in a Phase 1 clinical trial, Fusion's research and development capabilities, manufacturing and supply chain expertise, and our Fast-Clear™ linker technology provide a platform for creating new TATs and growing our pipeline."

Dr. Valliant continued, "Following a successful initial public offering in June, and achieving a regulatory milestone that triggered the second tranche of our Series B financing in May, we are well-positioned to reach significant inflection points in our clinical programs, expand our pipeline, and invest in our platform to create potent TATs."

"Our near-term priority is to initiate the multi-dosing portion of our Phase 1 trial of FPI-1434, and we are pleased to have received notice from both Health Canada and the U.S. Food and Drug Administration (FDA) that we are able to move forward with these plans," Dr. Valliant concluded.

Recent Highlights and Future Milestones

FPI-1434 Monotherapy

- Fusion has completed enrollment, dosing and the dose-limiting toxicity (DLT) evaluation period for the third patient cohort in the ongoing Phase 1 clinical trial of FPI-1434. Fusion plans to convene a Safety Review Committee (SRC) meeting in the third quarter of 2020 to evaluate the safety of the third patient single-dose cohort of 40kBq/kg (cohort three). Fusion anticipates Phase 1 single-dose safety and imaging data to be available in the fourth quarter of 2020.
- Fusion received notice from the FDA in May 2020 and a "No Objection Letter" from Health Canada in July 2020 indicating that investigation of the multiple-dose administration in the Phase 1 clinical trial of FPI-1434 may begin.
- Fusion anticipates reporting Phase 1 multiple-dose safety and imaging data, and the recommended Phase 2 dose/schedule, approximately nine to eighteen months after the commencement of this portion of the study.

FPI-1434 Combination Therapy

- Fusion is currently evaluating 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 initiating Phase 1 combination studies 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 to tumor sites 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 approximately six to twelve months after the Company fully resumes preclinical activities following interruptions caused by COVID-19.

Corporate Updates

- In June 2020, Fusion completed an initial public offering of 12,500,000 common shares at a public offering price of $17.00 per share. Gross proceeds of the offering, before deducting underwriting discounts and commissions and other offering expenses payable by Fusion, were $212.5 million.

- In May 2020, upon acceptance of the clinical trial protocol amendment to move from the single- to multiple-dose regimen of FPI-1434, the Company achieved a regulatory milestone associated with the Class B financing which triggered the closing of the second tranche of $62.5 million in gross proceeds.

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, most employees have transitioned to working remotely and travel has been restricted.

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 June 30, 2020, at this time, there is significant uncertainty relating to the trajectory of the pandemic. 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.

Second Quarter 2020 Financial Results

- **Cash Position:** As of June 30, 2020, Fusion held cash of $318.9 million, compared to cash of $65.3 million as of December 31, 2019. Fusion expects its cash as of June 30, 2020 will enable the Company to fund its operations into 2024.
- **R&D Expenses:** Research and development expenses for the second quarter of 2020 were $3.3 million, compared to $2.1 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 second quarter of 2020 were $4.0 million, compared to $1.8 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 second quarter of 2020, Fusion reported a net loss of $44.7 million, or $18.91 per share, compared with a net loss of $3.5 million, or $1.79 per share, for the same period in 2019. During the second quarter of 2020, Fusion recorded a non-cash charge of $31.6 million for the final fair value measurement of the Company's Class B preferred share tranche right liability. The fair value increased in the quarter due primarily to an increase in the fair value of the Class B preferred shares as a result of achieving specified milestones underlying the preferred share tranche rights. Fusion also recorded a non-cash charge of $6.1 million during the second quarter of 2020 for the final fair value measurement of the Company's Class B preferred share warrant liability. The fair value increased in the quarter due primarily to an increase in the fair value of the underlying Class B preferred shares resulting from the IPO. The tranche right liability and the warrant liability were reclassified to shareholders' equity during the second quarter of 2020. Excluding these non-cash charges, for the second quarter of 2020 net loss on a non-GAAP adjusted basis was $7.1 million.

Upcoming Events

- Fusion will present at the 2020 Wedbush PacGrow Healthcare Virtual Conference on Wednesday, August 12 at 9:10am EDT.
- Fusion will participate in a virtual "fireside chat" presentation at Morgan Stanley's 18th Annual Global Healthcare Conference on Thursday, September 17 at 11:00am EDT.

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 will be available on the Security 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)

	June 30, 2020	December 31, 2019
Assets		
Current assets:		
Cash	$ 318,892	$ 65,344
Restricted cash	280	280
Prepaid expenses and other current assets	960	929
Total current assets	320,132	66,553
Property and equipment, net	1,403	1,272
Deferred tax assets	78	78
Restricted cash	1,497	1,497
Total assets	$ 323,110	$ 69,400
Liabilities, Non-Controlling Interest, Convertible Preferred Shares and Shareholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 703	$ 830
Income taxes payable	278	117
Accrued expenses	6,629	3,326
Total current liabilities	7,610	4,273
Deferred rent, net of current portion	—	28
Preferred share tranche right liability	—	5,741
Income taxes payable, net of current portion	293	293
Special voting shares redemption right liability (Notes 2 and 6)	—	—
Total liabilities	7,903	10,335
Commitments and contingencies (Note 11)		
Non-controlling interest in Fusion Pharmaceuticals (Ireland) Limited (Notes 2 and 6)	—	20,961
Convertible preferred shares, no par value; 0 shares and 132,207,290 shares authorized as of June 30, 2020 and December 31, 2019, respectively; 0 shares and 73,125,790 shares issued and outstanding as of June 30, 2020 and December 31, 2019, respectively; aggregate liquidation preference of $0 and $77,965 as of June 30, 2020 and December 31, 2019, respectively	—	71,592
Shareholders' equity (deficit):		
Common shares, no par value, unlimited shares authorized as of June 30, 2020 and December 31, 2019; 41,664,044 and 1,929,555 shares issued and outstanding as of June 30, 2020 and December 31, 2019, respectively	—	—
Additional paid-in capital	405,032	1,286
Accumulated deficit	(89,825)	(34,774)
Total shareholders' equity (deficit)	315,207	(33,488)
Total liabilities, non-controlling interest, convertible preferred shares and shareholders' equity (deficit)	$ 323,110	$ 69,400

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,	
	2020	2019	2020	2019
Operating expenses:				
Research and development	$ 3,325	$ 2,137	$ 7,702	$ 4,978
General and administrative	3,988	1,771	8,315	2,942
Total operating expenses	7,313	3,908	16,017	7,920
Loss from operations	(7,313)	(3,908)	(16,017)	(7,920)
Other income (expense):				
Change in fair value of preferred share tranche right liability	(31,604)	222	(32,722)	222
Change in fair value of preferred share warrant liability	(6,065)	—	(6,399)	—
Interest income	22	148	169	148
Refundable investment tax credits	52	44	98	88
Other income (expense), net	325	56	128	105
Total other income (expense), net	(37,270)	470	(38,726)	563
Loss before provision for income taxes	(44,583)	(3,438)	(54,743)	(7,357)
Provision for income taxes	(150)	(18)	(212)	(32)
Net loss and comprehensive loss	(44,733)	(3,456)	(54,955)	(7,389)
Dividends paid to preferred shareholders in the form of warrants issued	—	—	(1,382)	—
Net loss attributable to common shareholders	$ (44,733)	$ (3,456)	$ (56,337)	$ (7,389)
Net loss per share attributable to common shareholders—basic and diluted	$ (18.91)	$ (1.79)	$ (26.23)	$ (3.89)
Weighted-average common shares outstanding—basic and diluted	2,366,198	1,928,933	2,147,876	1,901,109

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

	Six Months Ended June 30,	
	2020	2019
Cash flows from operating activities:		
Net loss	$ (54,955)	$ (7,389)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation expense	784	190
Depreciation and amortization expense	270	134
Non-cash rent expense	14	—
Change in fair value of preferred share tranche right liability	32,722	(222)

Change in fair value of preferred share warrant liability	6,399	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(103)	(46)
Accounts payable	(319)	(12)
Accrued expenses	1,209	525
Income taxes payable	162	(9)
Net cash used in operating activities	(13,817)	(6,829)
Cash flows from investing activities:		
Purchases of property and equipment	(382)	(151)
Net cash used in investing activities	(382)	(151)
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	(2,276)	—
Net cash provided by financing activities	267,747	52,187
Net increase in cash and restricted cash	253,548	45,207
Cash and restricted cash at beginning of period	67,121	29,080
Cash and restricted cash at end of period	$ 320,669	$ 74,287
Supplemental disclosure of cash flow information:		
Cash paid for income taxes	$ 50	$ 40
Supplemental disclosure of non-cash investing and financing activities:		
Purchases of property and equipment included in accounts payable and accrued expenses	$ —	$ 11
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	$ —
Offering costs included in accounts payable and accrued expenses	$ 2,296	$ —

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
GAAP Net loss and comprehensive loss	$ (44,733)	$ (3,456)	$ (54,955)	$ (7,389)
Adjustments				
Change in fair value of preferred share tranche right liability	(31,604)	222	(32,722)	222
Change in fair value of preferred share warrant liability	(6,065)	—	(6,399)	—
Non-GAAP Net loss and comprehensive loss	$ (7,064)	$ (3,678)	$ (15,834)	$ (7,611)

SOURCE Fusion Pharmaceuticals Inc.

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