

Fusion Pharmaceuticals Announces Fourth Quarter 2020 Financial Results And Business Update

- FPI-1434 Phase 1 study is progressing

- Recent transactions and partnerships expand and diversify Fusion's pipeline of targeted alpha therapies in development to treat a broad array of tumor types

HAMILTON, ON and BOSTON, March 25, 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 fourth quarter ended December 31, 2020 and provided an update on clinical and corporate developments.

"Advancing the Phase 1 clinical study of our lead program, FPI-1434, continues to be our primary focus," said Chief Executive Officer John Valliant, Ph.D. "We are working towards determining the recommended Phase 2 dose, and defining tumor-specific cohorts, which we expect to occur in the first half of 2022."

Dr. Valliant continued, "Employing Fusion's adaptable platform, we are expanding our pipeline of targeted alpha therapies using different targeting moieties to treat an array of cancers with high unmet medical need. The recent transactions with Ipsen and AstraZeneca expand and diversify our pipeline and underscore the growing interest in harnessing the power of alpha-emitting radiopharmaceuticals to create innovative precision cancer treatments for patients."

Recent Highlights and Future Milestones

Corporate Updates

- On March 2, Fusion [announced](#) it has entered into an asset purchase agreement (APA) to acquire Ipsen's intellectual property and assets related to IPN-1087. IPN-1087 is a small molecule targeting neurotensin receptor 1 (NTSR1), a protein expressed on multiple solid tumor types. Fusion intends to utilize its expertise and IPN-1087 to create an alpha-emitting radiopharmaceutical, FPI-2059, targeting solid tumors expressing NTSR1. The Company expects to submit an investigational new drug application in the first half of 2022.

FPI-1434 Monotherapy

- In December 2020, Fusion announced that the first patient had been dosed in the multi-dose portion of the Phase 1 study evaluating FPI-1434 in patients with advanced solid tumors. The multi-dose portion follows completion of the single-ascending dose portion of the Phase 1 study, which showed that FPI-1434 was generally well tolerated with no dose limiting toxicities or treatment-related serious adverse events reported to date. The multi-dose portion of the study is enrolling patients at sites in Canada, the United States and Australia. The current patient cohort is being dosed with FPI-1434 at 75kBq/kg with repeat cycles every six weeks up to allowable limits.
- Fusion anticipates reporting Phase 1 multi-dose safety and imaging data, and the recommended Phase 2 dose/schedule, in the first half of 2022.

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 second quarter of 2021.

Fourth Quarter 2020 Financial Results

- Cash and Investments:** As of December 31, 2020, Fusion held cash, cash equivalents and investments of \$299.5 million, compared to cash of \$65.3 million as of December 31, 2019. Fusion expects its cash, cash equivalents and investments as of December 31, 2020 will enable the Company to fund its operations through the end of 2023.
- R&D Expenses:** Research and development expenses for the fourth quarter of 2020 were \$5.0 million, compared to \$3.4 million for the same period in 2019. The increase was primarily related to increased employee-related costs associated with hiring and increases in clinical, preclinical and discovery activities, partially offset by lower manufacturing expenses.
- G&A Expenses:** General and administrative expenses for the fourth quarter of 2020 were \$6.6 million, compared to \$2.7 million for the same period in 2019. The increase was primarily related to increased salaries, benefits and stock compensation costs due to increased hiring, and increased professional and consulting fees as a result of public company activities.
- Net Loss:** For the fourth quarter of 2020, Fusion reported a net loss of \$13.4 million, or \$0.32 per share, compared with a net loss of \$8.2 million, or \$4.25 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 \$5.9 million for the fourth quarter of 2019.

Impact of COVID-19

While Fusion has commenced dosing in the multi-dosing portion of the Phase 1 clinical trial of FPI-1434, the Company has experienced moderate delays in patient recruitment and enrollment as a result 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.

At this time, there is significant uncertainty relating to the trajectory of the pandemic and whether it may cause further delays in patient study recruitment. 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. Fusion connects alpha particle emitting isotopes to 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. The Company is advancing a pipeline of targeted radiopharmaceutical cancer therapies for a broad array of tumor types based upon its proprietary platform technology.

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, 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 September 30, 2020 which is available on the Securities and Exchange Commission's website at www.sec.gov and Fusion's website at www.fusionpharma.com.

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

	December 31,	
	2020	2019
Assets		
Current assets:		
Cash and cash equivalents	\$ 90,517	\$ 65,344
Short-term investments	131,882	—
Prepaid expenses and other current assets	5,340	929
Restricted cash	425	280
Total current assets	228,164	66,553
Property and equipment, net	1,967	1,272
Deferred tax assets	653	78
Restricted cash	1,466	1,497
Long-term investments	77,082	—
Other non-current assets	1,344	—
Total assets	<u>\$ 310,676</u>	<u>\$ 69,400</u>
Liabilities, Non-Controlling Interest, Convertible Preferred Shares and Shareholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	\$ 3,399	\$ 830
Accrued expenses	4,659	3,326
Income taxes payable	2,799	117
Deferred revenue	1,000	—
Total current liabilities	11,857	4,273
Deferred rent, net of current portion	11	28
Deferred revenue, net of current portion	4,000	—
Preferred share tranche right liability	—	5,741
Income taxes payable, net of current portion	295	293
Special voting shares redemption right liability	—	—
Total liabilities	16,163	10,335
Commitments and contingencies		
Non-controlling interest in Fusion Pharmaceuticals (Ireland) Limited	—	20,961
Convertible preferred shares, no par value; 0 shares and 132,207,290 shares authorized as of December 31, 2020 and 2019, respectively; 0 shares and 73,125,790 shares issued and outstanding as of December 31, 2020 and 2019, respectively; aggregate liquidation preference of \$0 and \$77,965 as of December 31, 2020 and 2019, respectively	—	71,592
Shareholders' equity (deficit):		
Common shares, no par value, unlimited shares authorized as of December 31, 2020 and 2019; 41,725,797 shares and 1,929,555 shares issued and outstanding as of December 31, 2020 and 2019, respectively	—	—
Additional paid-in capital	407,672	1,286
Accumulated other comprehensive income	44	—
Accumulated deficit	(113,203)	(34,774)
Total shareholders' equity (deficit)	294,513	(33,488)
Total liabilities, non-controlling interest, convertible preferred shares and shareholders' equity (deficit)	<u>\$ 310,676</u>	<u>\$ 69,400</u>

FUSION PHARMACEUTICALS INC. CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS (In thousands, except share and per share amounts) (Unaudited)

	Three Months Ended December 31,		Year Ended
	2020	2019	2020
Operating expenses:			
Research and development	\$ 4,960	\$ 3,416	\$ 17,191
General and administrative	6,639	2,724	20,744
Total operating expenses	11,599	6,140	37,935
Loss from operations	(11,599)	(6,140)	(37,935)
Other income (expense):			
Change in fair value of preferred share tranche right liability	—	(2,275)	(32,722)
Change in fair value of preferred share warrant liability	—	—	(6,399)
Interest income (expense), net	78	181	327
Refundable investment tax credits	(139)	44	—

Other income (expense), net	859	22	1,007
Total other income (expense), net	798	(2,028)	(37,787)
Loss before provision for income taxes	(10,801)	(8,168)	(75,722)
Income tax provision	(2,584)	(38)	(2,611)
Net loss	\$ (13,385)	\$ (8,206)	\$ (78,333)
Unrealized gain on investments	45	—	44
Comprehensive loss	\$ (13,340)	\$ (8,206)	\$ (78,289)
Reconciliation of net loss to net loss attributable to common shareholders:			
Net loss	\$ (13,385)	\$ (8,206)	\$ (78,333)
Dividends paid to preferred shareholders in the form of warrants issued	—	—	(1,382)
Net loss attributable to common shareholders	(13,385)	(8,206)	(79,715)
Net loss per share attributable to common shareholders—basic and diluted	\$ (0.32)	\$ (4.25)	\$ (3.62)
Weighted-average common shares outstanding—basic and diluted	41,722,234	1,929,555	22,033,269

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

	Year Ended December 31,	
	2020	2019
Cash flows from operating activities:		
Net loss	\$ (78,333)	\$ (16,189)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation expense	3,368	618
Depreciation and amortization expense	482	290
Non-cash rent expense	25	(3)
Change in fair value of preferred share tranche right liability	32,722	(1,432)
Change in fair value of preferred share warrant liability	6,399	—
Amortization of premiums (accretion of discounts) on investments, net	410	—
Deferred tax benefit	(576)	(59)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(4,454)	259
Other non-current assets	(1,344)	—
Accounts payable	2,558	479
Accrued expenses	1,291	2,132
Deferred revenue	5,000	—
Income taxes payable	2,685	215
Net cash used in operating activities	(29,767)	(13,690)
Cash flows from investing activities:		
Purchases of investments	(219,030)	—
Maturities of investments	9,700	—
Purchases of property and equipment	(1,123)	(456)
Net cash used in investing activities	(210,453)	(456)
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)	—
Proceeds from issuance of common shares upon exercise of stock options	56	—
Net cash provided by financing activities	265,507	52,187
Net increase in cash, cash equivalents and restricted cash	25,287	38,041
Cash, cash equivalents and restricted cash at beginning of period	\$ 67,121	\$ 29,080
Cash, cash equivalents and restricted cash at end of period	\$ 92,408	\$ 67,121
Supplemental disclosure of cash flow information:		
Cash paid for income taxes	\$ 501	\$ 95
Supplemental disclosure of non-cash investing and financing activities:		
Purchases of property and equipment included in accounts payable and accrued expenses	\$ 35	\$ 24
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	\$ —
Issuance of common shares upon net settlement of stock option exercise	\$ —	\$ 57

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

	Three Months Ended		Year Ended	
	December 31,		December 31:	
	2020	2019	2020	
GAAP Net loss	\$ (13,385)	\$ (8,206)	\$ (78,333)	\$
Less: Adjustments				
Change in fair value of preferred share tranche right liability	—	(2,275)	(32,722)	
Change in fair value of preferred share warrant liability	—	—	(6,399)	
Non-GAAP Net loss	\$ (13,385)	\$ (5,931)	\$ (39,212)	\$

SOURCE Fusion Pharmaceuticals Inc.

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<https://ir.fusionpharma.com/2021-03-25-Fusion-Pharmaceuticals-Announces-Fourth-Quarter-2020-Financial-Results-and-Business-Update>