Fusion Pharmaceuticals Announces Fourth Quarter 2021 Financial Results And Clinical Program Updates

- Company is advancing first targeted alpha therapy (TAT) candidate under collaboration with AstraZeneca

- Recently signed research collaborations support expansion of pipeline into peptide-based radiopharmaceuticals

- Company continues to build a diversified pipeline of TATs and advance supply chain capabilities as Phase 1 data for FPI-1434 is anticipated to be reported in second half of 2022

HAMILTON, Ontario & BOSTON, March 17, 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 fourth quarter ended December 31, 2021 and provided an update on clinical and corporate developments.

Chief Executive Officer John Valliant, Ph.D. commented, "In 2021, we made progress leveraging our platform technology and research engine to build a diverse pipeline of targeted alpha therapies (TATs) from different classes of targeting molecules to pursue validated cancer targets in areas of high unmet medical need."

Dr. Valliant continued, "We continue to execute on our Phase 1 trial of FPI-1434 in patients with solid tumors, and look forward to reporting data from this trial in the second half of this year. Our subsequent programs are progressing, with the investigational new drug application (IND) for FPI-1966 cleared in 2021, and the submission of an IND for FPI-2059, our first small molecule program, expected in the first half of this year. In addition, under our collaboration, we have agreed with AstraZeneca to progress to IND-enabling studies a new bispecific antibody-based TAT. We also recently entered two strategic partnerships to discover novel, peptide-based radiopharmaceuticals, both demonstrating the versatility and potential applicability of the Fusion platform. In parallel, we have expanded our leadership team, deepening our radiopharmaceutical and oncology expertise, and progressed our manufacturing and actinium supply initiatives, supporting our pipeline growth and clinical plans. Amid a resurgence of excitement about the potential for radiopharmaceuticals becoming a pillar of cancer therapy, Fusion is well-positioned as a leader in the space."

Clinical Update

FPI-1434

In the Phase 1 study, Fusion is exploring various dosing 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 continues to anticipate reporting Phase 1 safety, pharmacokinetics, and imaging data, including any evidence of anti-tumor activity, and details on the dosing paradigm, in the second half of 2022. 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, 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 now expects to dose the first patient in the second quarter of 2022 rather than the first quarter and expects preliminary pharmacokinetic and imaging data from the first patient cohort in the second quarter of 2023. The shift is a result of delays in study site initiations related to the COVID-19 pandemic.

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 solid tumors. FPI-2059 combines Ipsen's IPN-1087 (previously studied as a beta-emitting radiopharmaceutical), 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 January, Fusion announced the nomination of the first TAT candidate under the Company's collaboration agreement with AstraZeneca. Both companies will jointly develop through a Phase 1 study the novel TAT which utilizes Fusion's Fast-Clear™ linker technology to radiolabel an AstraZeneca-owned bispecific antibody with the alpha-emitting isotope, actinium-225. Fusion and AstraZeneca are continuing to progress up to two additional TATs and up to five combination therapies with Fusion's TATs.
- Also in January, Fusion announced the company entered into a strategic research collaboration with 48 Hour Discovery Inc. and Pepscan Therapeutics B.V. to discover novel, peptide-based radiopharmaceuticals for the treatment of various solid tumors.

Fourth Quarter 2021 Financial Results

- **Cash and Investments:** As of December 31, 2021, Fusion held cash, cash equivalents and investments of $220.8 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 December 31, 2021 will enable the Company to fund its operations through the end of 2023.
- **Collaboration Revenue:** For the fourth quarter of 2021, Fusion recorded $0.6 million of revenue under the AstraZeneca collaboration agreement.
- **R&D Expenses:** Research and development expenses for the fourth quarter of 2021 were $11.8 million, compared to $5.0 million for the same period in 2020. The increase was primarily related to costs associated with manufacturing for the Company's clinical and preclinical programs, as well as increased clinical costs associated with FPI-1966.
- **G&A Expenses:** General and administrative expenses for the fourth quarter of 2021 were $6.3 million, compared to $6.6 million for the same period in 2020. The decrease was primarily related to a reduction in professional fees and other costs associated with the Company's 2020 initial public offering, partially offset by increases in personnel-related expenses.
- **Net Loss:** For the fourth quarter of 2021, Fusion reported a net loss of $17.2 million, or $0.40 per share, compared with a net loss of $13.4 million, or $0.32 per share, for the same period in 2020.

Impact of COVID-19

Fusion is experiencing material delays in patient recruitment, enrollment and study site initiations 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. 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), advancing to a Phase 1 study following the recent investigational new drug (IND) clearance; and FPI-2059, a small molecule targeting neurotensin receptor 1 (NTSR1). 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. Fusion and Hamilton, Ontario-based McMaster University are building a current Good Manufacturing Practice (GMP) compliant radiopharmaceutical manufacturing facility designed to support manufacturing of the Company's growing pipeline of TATs.

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 clinical 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 September 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.

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

	December 31, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 52,898	$ 90,517
Accounts receivable	357	—
Short-term investments	147,897	131,882
Prepaid expenses and other current assets	9,941	5,340
Restricted cash	669	425
Total current assets	211,762	228,164
Property and equipment, net	2,967	1,967
Deferred tax assets	1,645	653
Restricted cash	1,222	1,466
Long-term investments	19,987	77,082
Operating lease right-of-use assets	6,486	—
Other non-current assets	8,202	1,344
Total assets	$ 252,271	$ 310,676
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	$ 2,195	$ 3,399
Accrued expenses	7,563	4,659
Income taxes payable	—	2,799
Deferred revenue	1,538	1,000
Operating lease liabilities	1,215	—
Total current liabilities	12,511	11,857
Deferred rent, net of current portion	—	11
Income taxes payable, net of current portion	297	295
Deferred revenue, net of current portion	2,500	4,000
Operating lease liabilities, net of current portion	5,507	—
Total liabilities		

Shareholders' equity:	20,815	16,163
Common shares, no par value, unlimited shares authorized as of December 31, 2021 and 2020; 43,073,727 shares and 41,725,797 shares issued and outstanding as of December 31, 2021 and 2020, respectively	—	—
Additional paid-in capital	425,821	407,672
Accumulated other comprehensive (loss) income	(115)	44
Accumulated deficit	(194,250)	(113,203)
Total shareholders' equity	231,456	294,513
Total liabilities and shareholders' equity	$ 252,271	$ 310,676

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 De
	2021	2020	2021
Collaboration revenue	$ 594	$ —	$ 1,440
Operating expenses:			
Research and development	11,811	4,960	56,357
General and administrative	6,336	6,639	27,098
Total operating expenses	18,147	11,599	83,455
Loss from operations	(17,553)	(11,599)	(82,015)
Other income (expense):			
Change in fair value of preferred share tranche right liability	—	—	—
Change in fair value of preferred share warrant liability	—	—	—
Interest income, net	81	78	381
Other income, net	63	720	469
Total other income (expense), net	144	798	850
Loss before benefit (provision) for income taxes	(17,409)	(10,801)	(81,165)
Income tax benefit (provision)	173	(2,584)	118
Net loss	$ (17,236)	$ (13,385)	$ (81,047)
Unrealized (loss) gain on investments	(178)	45	(159)
Comprehensive loss	$ (17,414)	$ (13,340)	$ (81,206)
Reconciliation of net loss to net loss attributable to common shareholders:			
Net loss	$ (17,236)	$ (13,385)	$ (81,047)
Dividends paid to preferred shareholders in the form of warrants issued	—	—	—
Net loss attributable to common shareholders	(17,236)	(13,385)	(81,047)
Net loss per share attributable to common shareholders—basic and diluted	$ (0.40)	$ (0.32)	$ (1.90)
Weighted-average common shares outstanding—basic and diluted	43,066,953	41,722,234	42,598,843

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

	Year Ended December 31,	
	2021	2020
Cash flows from operating activities:		
Net loss	$ (81,047)	$ (78,333)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation expense	8,603	3,368
Depreciation and amortization expense	634	482
Non-cash lease expense	1,073	25
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 on investments, net	1,653	410
Deferred tax benefit	(991)	(576)
Common shares issued to acquire in-process research & development	8,924	—
Foreign exchange loss	6	—
Changes in operating assets and liabilities:		
Accounts receivable	(357)	—
Prepaid expenses and other current assets	(4,628)	(4,454)
Other non-current assets	(6,582)	(1,344)
Accounts payable	(1,183)	2,558
Accrued expenses	2,740	1,291
Deferred revenue	(962)	5,000
Income taxes payable	(2,797)	2,685
Operating lease liabilities	(826)	—
Net cash used in operating activities	(75,740)	(29,767)
Cash flows from investing activities:		
Purchases of investments	(172,469)	(219,030)
Sales and maturities of investments	211,734	9,700
Purchases of property and equipment	(1,491)	(1,123)
Net cash provided by (used in) investing activities	37,774	(210,453)
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	(275)	(4,572)
Proceeds from issuance of common shares upon exercise of stock options and ESPP	622	56

Net cash provided by financing activities	347	265,507
Net (decrease) increase in cash, cash equivalents and restricted cash	(37,619)	25,287
Cash, cash equivalents and restricted cash at beginning of period	$ 92,408	$ 67,121
Cash, cash equivalents and restricted cash at end of period	$ 54,789	$ 92,408
Supplemental disclosure of cash flow information:		
Cash paid for income taxes	$ 3,961	$ 501
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	$ 178	$ 35
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

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https://ir.fusionpharma.com/2022-03-17-Fusion-Pharmaceuticals-Announces-Fourth-Quarter-2021-Financial-Results-and-Clinical-Program-Updates