Inhibrx Reports Fourth Quarter and Fiscal Year 2020 Financial Results and Announces Phase 1 Single Agent Dose Escalation Results for INBRX-105, a Novel Targeted 4-1BB Agonist

SAN DIEGO, March 12, 2021 /PRNewswire/ -- Inhibrx, Inc. (Nasdaq: INBX), a biotechnology company with four clinical programs in development, today reported financial results for the fourth quarter and fiscal year 2020, and announced results from the single agent dose escalation of the Phase 1 study of INBRX-105.

Mark Lappe, Inhibrx's CEO commented, "2020 was a transformative year for Inhibrx. We made substantive advances in our four clinical programs across oncology and orphan disease, continued to progress our pre-clinical pipeline, and successfully completed an initial public offering."

Phase 1 Dose Escalation Results for INBRX-105

INBRX-105 is a precisely engineered multi-specific therapeutic candidate based on our single domain antibody (sdAb) platform that is designed to agonize 4-1BB selectively in the presence of programmed death ligand 1 (PD-L1), a protein that is typically found in the tumor microenvironment and lymphoid tissues.

The study is a first-in-human, multicenter, open-label, non-randomized, Phase 1 trial in patients with locally advanced or metastatic solid tumors. The trial is designed to determine the safety profile and identify the maximum tolerated dose (MTD) and/or recommended Phase 2 dose of INBRX-105 administered as a single agent or in combination with Keytruda® (pembrolizumab), a programmed death receptor-1 (PD-1) checkpoint inhibitor. Single agent dose escalation was completed with a total of 32 patients enrolled. We observed dose-limiting toxicities, which were consistent with immune related adverse events (for example, hepatitis, arthritis and myalgia/hyperthyroidism) at several dose levels and determined the 1 mg/kg dose level as the MTD of INBRX-105. Patients were not pre-screened for PD-L1 expression. Eight out of 18 evaluable patients (44%) receiving INBRX-105 at dose levels equal to or greater than 0.1 mg/kg achieved stable disease, with the greatest reduction in tumor volume observed to be 20% by RECISTv1.1. The longest duration on treatment with INBRX-105 was 41 weeks, or approximately nine and a half months. Notably, seven patients with stable disease tested positive for PD-L1 expression, with a minimum of 1% positivity as determined by immunohistochemistry (Range 1 to 95%), and the results of one patient are pending. Four of these eight patients were refractory to or progressed on prior PD-1 checkpoint inhibitors.

We expect to achieve the maximal therapeutic benefit of INBRX-105 in combination with PD-1 checkpoint blockade. In our preclinical studies we observed that acute exposure to PD-L1 dependent 4-1BB agonism was sufficient to derive maximal anti-tumor activity when co-dosed with another PD-1 blocking agent at a target saturating dose. As such, a dose escalation cohort of INBRX-105 in combination with Keytruda® is targeted to initiate enrollment during the second quarter of 2021 and we expect to announce initial data during the fourth quarter of 2021.

Financial Results

- ***Cash and Cash Equivalents***. Cash and cash equivalents totaled $128.7 million as of December 31, 2020, compared to $11.5 million as of December 31, 2019. Cash and cash equivalents totaled $111.3 million as of February 28, 2021.
- ***R&D Expense***. Research and development expense was $17.7 million during the fourth quarter of 2020, as compared to $12.3 million during the fourth quarter of 2019. Research and development expense was $73.5 million during the fiscal year 2020, as compared to $47.9 million during the fiscal year 2019. These increases were primarily due to an increase in contract manufacturing expense for scale-up activities performed by Inhibrx's contract development and manufacturing organization partners for its INBRX-109 and INBRX-101 programs. Additionally, clinical research organization costs increased due to the progression of its Phase 1 trials.
- ***G&A Expense***. General and administrative, or G&A, expense was $2.2 million during the fourth quarter of 2020, as compared to $1.7 million during the fourth quarter of 2019. G&A expense was $6.8 million during the fiscal year 2020, as compared to $6.3 million during the fiscal year 2019. These increases were primarily due to increases in Inhibrx's personnel-related expenses due to increased headcount and increased rent expense under its amended building lease.
- ***Net Loss.*** Net loss was $17.6 million during the fourth quarter of 2020, or a net loss per share of $0.47, as

compared to a net loss of $16.3 million during the fourth quarter of 2019, or a net loss per share of $0.90. Net loss was $76.1 million during the fiscal year 2020, or a net loss per share of $3.01, as compared to a net loss of $51.4 million during the fiscal year 2019, or a net loss per share of $2.83.

Inhibrx Corporate Presentation

Inhibrx has also updated its corporate presentation which is available on the "Investors" section of its website at www.inhibrx.com.

About the Inhibrx sdAb Platform

Inhibrx utilizes diverse methods of protein engineering in the construction of therapeutic candidates that can address the specific requirements of complex target and disease biology. A key tool for this effort is the Inhibrx proprietary sdAb platform, which enables the development of therapeutic candidates with attributes superior to other monoclonal antibody and fusion protein approaches. This platform allows the combination of multiple binding units in a single molecule, enabling the creation of therapeutic candidates with defined valency or multiple specificities that can achieve enhanced cell signaling or conditional activation. An additional benefit of this platform is that these optimized, multi-functional entities can be manufactured using the established processes that are commonly used to produce therapeutic proteins.

About Inhibrx, Inc.

Inhibrx is a clinical-stage biotechnology company focused on developing a broad pipeline of novel biologic therapeutic candidates in oncology and orphan diseases. Inhibrx utilizes diverse methods of protein engineering to address the specific requirements of complex target and disease biology, including its proprietary sdAb platform. Inhibrx has collaborations with bluebird bio, Bristol-Myers Squibb and Chiesi. For more information, please visit www.inhibrx.com.

Forward Looking Statements

Inhibrx cautions you that statements contained in this press release regarding matters that are not historical facts are forward-looking statements. These statements are based on Inhibrx's current beliefs and expectations. These forward-looking statements include, but are not limited to, statements regarding: future clinical development Inhibrx's therapeutic candidates, including statements regarding expected therapeutic benefit, the timing of future clinical development and evaluations and judgments regarding Inhibrx's therapeutic candidates. Actual results may differ from those set forth in this press release due to the risks and uncertainties inherent in Inhibrx's business, including, without limitation, risks and uncertainties regarding: the initiation, timing, progress and results of its preclinical studies and clinical trials, and its research and development programs; its ability to advance therapeutic candidates into, and successfully complete, clinical trials; its interpretation of initial, interim or preliminary data from its clinical trials, including interpretations regarding disease control and disease response; the timing or likelihood of regulatory filings and approvals; the successful commercialization of its therapeutic candidates, if approved; the pricing, coverage and reimbursement of its therapeutic candidates, if approved; its ability to utilize its technology platform to generate and advance additional therapeutic candidates; the implementation of its business model and strategic plans for its business and therapeutic candidates; its ability to successfully manufacture therapeutic candidates for clinical trials and commercial use, if approved; its ability to contract with third-party suppliers and manufacturers and their ability to perform adequately; the scope of protection it is able to establish and maintain for intellectual property rights covering its therapeutic candidates; its ability to enter into strategic partnerships and the potential benefits of these partnerships; its estimates regarding expenses, capital requirements and needs for additional financing and financial performance; its expectations regarding the impact of the COVID-19 pandemic on its business; and other risks described in Inhibrx's filings with the U.S. Securities and Exchange Commission (the "SEC"), including under the heading "Risk Factors" in Inhibrx's Quarterly Report on Form 10-Q for the period ended September 30, 2020, as filed with the SEC. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof, and Inhibrx undertakes no obligation to update these statements to reflect events that occur or circumstances that exist after the date hereof. All forward-looking statements are qualified in their entirety by this cautionary statement, which is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995.

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Condensed Consolidated Statements of Operations
(In thousands, except per share data)

	THREE MONTHS ENDED DECEMBER 31,		YEAR ENDED DECEMBER 31,	
	2020	2019	2020	2019
Revenue:				
License fee revenue	$ 2,776	$ 267	$ 12,808	$ 9,093
Grant revenue	—	(4)	80	4,118
Total revenue	2,776	263	12,888	13,211
Operating expenses:				
Research and development	17,668	12,283	73,495	47,907
General and administrative	2,215	1,673	6,836	6,257
Abandoned offering costs	—	2,761	—	2,761
Total operating expenses	19,883	16,717	80,331	56,925
Loss from operations	(17,107)	(16,454)	(67,443)	(43,714)
Total other income (expense)	(539)	149	(8,191)	(6,788)
Provision for income taxes	3	—	3	898
Loss on equity method investment	—	—	487	—
Net loss	(17,649)	(16,305)	$ (76,124)	$ (51,400)
Net loss per share, basic and diluted	$ (0.47)	$ (0.90)	$ (3.01)	$ (2.83)
Weighted-average shares of common stock outstanding, basic and diluted	37,712	18,154	25,261	18,154

Inhibrx, Inc
Condensed Consolidated Balance Sheets
(In thousands)

	AS OF DECEMBER 31,	
	2020	2019
Cash and cash equivalents	$ 128,664	$ 11,540
Other current assets	3,508	4,021
Non-current assets	11,568	10,928
Total assets	$ 143,740	26,489
Debt, current and non-current	$ 29,244	$ 3,563
Other current liabilities	31,399	17,007
Convertible notes	—	30,367
Other non-current liabilities	7,624	9,614
Total liabilities	68,267	60,551
Convertible preferred stock	—	59,507
Stockholders' equity (deficit)	75,473	(93,569)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	$ 143,740	$ 26,489

SOURCE Inhibrx, Inc.

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https://inhibrx.investorroom.com/2021-03-12-Inhibrx-Reports-Fourth-Quarter-and-Fiscal-Year-2020-Financial-Results-and-Announces-Phase-1-Single-Agent-Dose-Escalation-Results-for-INBRX-105-a-Novel-Targeted-4-1BB-Agonist