

March 31, 2022



# Inhibikase Therapeutics Reports Full Year 2021 Financial Results and Highlights Recent Period Activity

BOSTON and ATLANTA, March 31, 2022 /PRNewswire/ -- Inhibikase Therapeutics, Inc. (Nasdaq: IKT) (Inhibikase or Company), a clinical-stage pharmaceutical company developing therapeutics to modify the course of Parkinson's disease and related disorders, today reported financial results for the full year ended December 31, 2021 and highlighted recent developments.

"2021 was an important year for Inhibikase as we advanced our lead program IkT-148009 for Parkinson's disease into the clinic, continued to develop our early-stage pipeline programs and strengthened our balance sheet to support our development efforts well into 2023," commented Dr. Milton H. Werner, President and Chief Executive Officer of Inhibikase. "Just recently, we presented results from our Phase 1 and 1b study of IkT-148009 in patients with mild to moderately advanced Parkinson's disease at the annual AD/PD™ meeting. We believe these data continue to validate the safety and therapeutic potential of IkT-148009. As we look ahead, we hope to share more about our development strategy for this program including the upcoming Phase 2a study at our upcoming virtual KOL investor event on April 20<sup>th</sup>. Looking to our earlier programs, we are also continuing to advance IkT-148009 in animal models of Multiple Systems Atrophy (MSA), as well as plan to submit our IND application for IkT-001Pro, both in the second quarter. We view 2022 as a year of execution across our pipeline and look forward to providing updates throughout the year as we seek to improve the lives of patients suffering from a devastating neurodegenerative disease."

## Recent Developments and Upcoming Milestones:

- **Phase 1b clinical trial of IkT-148009** The Phase 1b study is a 3:1 randomized, placebo-controlled dose escalation trial evaluating the safety, tolerability, and pharmacokinetics of seven-day dosing of IkT-148009 at three escalating dose levels. The study is also assessing motor and non-motor function, gut motility, and measures of alpha-synuclein aggregate clearance as exploratory endpoints. In March, the Company presented data from the first cohort at the Alzheimer's & Parkinson's Diseases Conference (AD/PD™). Data demonstrated that the safety and tolerability profile in patients closely matched that of older healthy volunteers. Pharmacokinetics of IkT-148009 in volunteers and subjects was also similar, indicating that IkT-148009 pharmacology is consistent across the patient groups and penetrates the Central Nervous System. The Company expects to complete dosing of the Phase 1b study in the second quarter of 2022 and present full data at a medical meeting later this year.

- **Phase 1 dose escalation of IKT-148009 in older and elderly healthy volunteers:** Inhibikase continues to evaluate IKT-148009 in older and elderly healthy volunteers as part of the Phase 1 study. The Company has completed dose escalation studies through 325 mg. To date, no clinically significant adverse events have been observed at any dose.
- **Phase 2a clinical study for IKT-148009 in patients with Parkinson's Disease:** Inhibikase expects to dose the first patient in a Phase 2a study of IKT-148009 in untreated Parkinson's Disease in the second quarter of 2022, subject to agreements with the FDA. The 3:1 randomized, double-blind, twelve-week dosing trial will evaluate the safety and tolerability of three doses of IKT-148009 in up to 120 patients diagnosed with Parkinson's disease who have not yet progressed to the need for symptomatic therapy. The trial will also measure motor and non-motor function inside and outside of the brain as secondary endpoints and evaluate whether treatment with IKT-148009 leads to a reduction or clearance of pathogenic alpha-synuclein aggregates as exploratory endpoints.
- **Investigational New Drug application (IND) for IKT-001Pro for stable-phase Chronic Myelogenous Leukemia (CML):** IKT-001Pro is the Company's prodrug formulation of Imatinib mesylate, designed as a potentially safer, better tolerated treatment for Imatinib-sensitive cancers such as stable-phase Chronic Myeloid Leukemia (CML). The Company is completing clinical batch manufacturing of pill formulated IKT-001Pro and conducting required stability studies and expects to submit the IND for IKT-001Pro in the second quarter of 2022. The Company expects to commence bioequivalence studies in accordance with the 505(b)(2) regulatory pathway agreements with the FDA.
- **Preclinical studies evaluating IKT-148009 in animal models of Multiple System Atrophy (MSA) in preparation for Phase 2 clinical studies:** Inhibikase expects to report preclinical data studying IKT-148009 in at least one of two animal models of MSA prior to dosing of MSA patients. The studies are evaluating whether inhibition of the Abelson Tyrosine Kinase, or c-Abl, could have a therapeutic benefit in MSA. The potential role of c-Abl in the disease process was highlighted in the Company's recent publication published in the peer reviewed journal *Neurobiology of Disease*<sup>[1]</sup>. Depending on the preclinical results in animal models of MSA and subject to agreement with the FDA and equivalent regulatory bodies in the European Union, Inhibikase may advance IKT-148009 into a Phase 2a clinical study in the third quarter of 2022.

## Upcoming Events:

### Virtual KOL Investor Event

Date: April 20, 2022

Time: 10:00am ET

Registration Link: <https://www.inhibikase.com/investors>

Inhibikase's executive leadership team and featured Key Opinion Leaders will host a virtual presentation highlighting the Company's recent clinical progress including a review of the

recently reported Phase 1 data for its lead asset, IKT-148009 as well as an overview of the upcoming Phase 2 program. Additional presentations will highlight the current unmet need and competitive landscape in Parkinson's disease.

## **Full Year 2021 Financial Results**

**Grant Revenue:** Grant revenue was \$3.1 million for the year ended December 31, 2021 compared to \$0.7 million in the prior year. The increase was driven by increased grant research activity during 2021 compared to 2020. During 2020, the Company's focus was shifted toward advancing its Phase I clinical trials which did not result in grant revenue. The Company utilized its working capital and personnel resources in 2021 to carry on its Phase I clinical trial in addition to its grant research activity.

**R&D Expenses:** Research and development expenses were \$11.4 million for the year ended December 31, 2021 compared to \$0.9 million in the year ended December 31, 2020. The increase was primarily due to a full year of increased activity in our Parkinson's disease Phase I clinical trial.

**SG&A Expenses:** Selling, general and administrative expenses for the year ended December 31, 2021 were \$6.5 million compared to \$2.6 million for the year ended December 31, 2020. The increase was primarily due to increased liability insurance, legal and accounting fees, board costs, investor relations and consulting fees associated with operating for the first full year as a public company.

**Net Loss:** Net loss for the year ended December 31, 2021 was \$14.8 million, or \$0.81 per share, compared to a net loss of \$2.8 million, or \$0.35 per share in the year ended December 31, 2020.

**Cash Position:** Cash and cash equivalents were \$40.8 million as of December 31, 2021. The Company expects that existing cash and cash equivalents will be sufficient to fund its operating expenses and capital expenditure requirements into the third quarter of 2023.

## **About Inhibikase ([www.inhibikase.com](http://www.inhibikase.com))**

Inhibikase Therapeutics, Inc. (Nasdaq: IKT) is a clinical-stage pharmaceutical company developing therapeutics for Parkinson's disease and related disorders. Inhibikase's multi-therapeutic pipeline focuses on neurodegeneration and its lead program IKT-148009, an Abelson Tyrosine Kinase (c-Abl) inhibitor, targets the treatment of Parkinson's disease inside and outside the brain. Its multi-therapeutic pipeline is pursuing Parkinson's-related disorders of the brain and GI tract, orphan indications related to Parkinson's disease such as Multiple System Atrophy, and drug delivery technologies for kinase inhibitors such as IKT-001Pro, a prodrug of the anticancer agent Imatinib that the Company believes will provide a better patient experience with fewer on-dosing side-effects. The Company's RAMP™ medicinal chemistry program has identified a number of follow-on compounds to IKT-148009 to be potentially applied to other cognitive and motor function diseases of the brain. Inhibikase is headquartered in Atlanta, Georgia with offices in Boston, Massachusetts.

## **Social Media Disclaimer**

Investors and others should note that we announce material financial information to our investors using our investor relations website, press releases, SEC filings and public conference calls and webcasts. The Company intends to also

use [Twitter](#), [Facebook](#), [LinkedIn](#) and [YouTube](#) as a means of disclosing information about the Company, its services and other matters and for complying with its disclosure obligations under Regulation FD.

## Forward-Looking Statements

This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking terminology such as "believes," "expects," "may," "will," "should," "anticipates," "plans," or similar expressions or the negative of these terms and similar expressions are intended to identify forward-looking statements. These forward-looking statements are based on Inhibikase's current expectations and assumptions. Such statements are subject to certain risks and uncertainties, which could cause Inhibikase's actual results to differ materially from those anticipated by the forward-looking statements. Important factors that could cause actual results to differ materially from those in the forward-looking statements are set forth in Inhibikase's filings with the SEC, including its annual report on Form 10-K for the year ended December 31, 2021, including under the caption "Risk Factors." Any forward-looking statement in this release speaks only as of the date of this release. Inhibikase undertakes no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future developments or otherwise, except as may be required by any applicable securities laws.

<sup>1</sup> doi: 10.1016/j.nbd.2020.105184

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## Inhibikase Therapeutics, Inc. Consolidated Balance Sheets

	December 31, 2021	December 31, 2020
<b>Assets</b>		
Current assets:		
Cash	\$ 40,750,133	\$ 13,953,513
Accounts receivable	110,141	—
Prepaid research and development	107,000	774,356
Prepaid expenses and other current assets	1,502,725	54,837
Total assets	<u>\$ 42,469,999</u>	<u>\$ 14,782,706</u>
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 1,089,778	\$ 1,720,680
Accrued expenses and other current liabilities	2,715,761	632,934

Deferred revenue	—	2,325,741
Notes payable	248,911	42,534
Total	4,054,450	4,721,889
Notes payable, net of current portion	—	276,461
Total liabilities	4,054,450	4,998,350
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.001 par value; 10,000,000 shares authorized at December 31, 2021 and 2020; 0 shares issued and outstanding at December 31, 2021 and 2020	—	—
Common stock, \$0.001 par value; 100,000,000 shares authorized; 25,155,198 and 10,050,849 shares issued and outstanding at December 31, 2021 and 2020	25,155	10,051
Additional paid-in capital	68,208,081	24,805,929
Accumulated deficit	(29,817,687)	(15,031,624)
Total	38,415,549	9,784,356
Total liabilities and stockholders' equity	\$ 42,469,999	\$ 14,782,706

**Inhibikase Therapeutics, Inc.**  
**Consolidated Statements of Operations**

	<b>Year ended December 31,</b>	
	<b>2021</b>	<b>2020</b>
Revenue:		
Grant revenue	\$ 3,100,605	\$ 698,468
Total revenue	3,100,605	698,468
Costs and expenses:		
Research and development	11,359,104	893,802
Selling, general and administrative	6,507,641	2,623,158
Total costs and expenses	17,866,745	3,516,960
Loss from operations	(14,766,140)	(2,818,492)
Interest expense	(19,923)	(29,402)
Net loss	\$ (14,786,063)	\$ (2,847,894)
Net loss per share – basic and diluted	\$ (0.81)	\$ (0.35)
Weighted-average number of common shares – basic and diluted	18,209,198	8,212,581

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