

March 31, 2023



Inhibikase Therapeutics Reports Full Year 2022 Financial Results and Highlights

Recent Period Activity

BOSTON and ATLANTA, March 31, 2023 /PRNewswire/ -- Inhibikase Therapeutics, Inc. (Nasdaq: IKT) (Inhibikase or Company), a clinical-stage pharmaceutical company developing protein kinase inhibitor therapeutics to modify the course of Parkinson's disease ("PD"), Parkinson's-related disorders and other diseases of the Abelson Tyrosine Kinases, today reported financial results for the full year ended December 31, 2022 and highlighted recent developments.

"2022 was an important year for Inhibikase as we continued to advance and validate our lead asset IKT-148009 in the clinic and through data presentations at several notable scientific and industry conferences. While the FDA clinical hold on our IKT-148009 programs was an unexpected challenge, we were pleased to announce that the FDA lifted the hold on our Parkinson's program in January 2023 and on Multiple System Atrophy, or MSA, in early March, 2023. As such, we are working diligently to restart the Phase 2a '201' clinical trial and have begun planning for the Phase 2 program in MSA," said Dr. Milton H. Werner, President and Chief Executive Officer of Inhibikase. "We will continue making progress across our pipeline in 2023. In addition to advancing IKT-148009 in the '201' trial, we expect to complete our '501' bioequivalence study for IKT-001Pro, our prodrug formulation of imatinib mesylate for Stable-Phase Chronic Myelogenous Leukemia. We look forward to providing updates throughout the year as we seek to bring our disease-modifying therapeutics to patients living with neurodegenerative diseases and cancer."

Recent Developments and Upcoming Milestones:

- **Full clinical hold on IKT-148009 in Parkinson's disease programs lifted by the U.S. Food and Drug Administration (FDA):** In January 2023, Inhibikase announced that the Phase 2a '201' clinical trial for IKT-148009 would resume immediately at the 50 and 100 mg doses following the lift of the full clinical hold by the FDA. The Agency requested that the Company measure additional safety and pharmacokinetic data in healthy subjects at the 200mg dose ahead of implementation in the '201' trial, measurements that are nearing completion. In addition, the Company will broaden its ocular monitoring program to measure visual acuity and examine the cornea and lens to complement the examination of the retina, macula and fundus that was already part of the ocular monitoring program in the trial. This monitoring program is consistent with the ocular pathology monitoring programs of other approved protein kinase inhibitors. The Company is re-opening clinical trial sites and initiating screening and enrollment of patients on a rolling basis.

- **Full clinical hold on IKT-148009 in MSA lifted by the U.S.FDA** In March 2023, Inhibikase announced that the Investigational New Drug (IND) application for the Phase 2 trial of IKT-148009 in MSA was lifted and the IND opened. This 6-month trial is currently in the planning stages, awaiting the outcome of prophylactic and therapeutic model studies evaluating the potential benefit of IKT-148009 as a treatment for MSA.
- **Highlighted publication demonstrating the potential of IKT-148009 as a disease-modifying therapy for Parkinson's disease and related disorders:** In January 2023, Inhibikase announced the publication of a paper entitled "*The c-Abl inhibitor IKT-148009 suppresses neurodegeneration in mouse models of heritable and sporadic Parkinson's disease,*" in the *Journal of Science Translational Medicine* (DOI: 10.1126/scitranslmed.abp9352). The published work illustrates the neurodegenerative functional screen that led to the discovery of IKT-148009 as well as data from once daily oral administration of IKT-148009 in several animal models that mimicked the rate of disease progression observed in human PD. Results from these studies demonstrated the ability of IKT-148009 to halt disease progression, drive functional recovery and protect neurons in the brain from degradation. Therapeutic benefit in these models was accompanied by substantial reduction of alpha-synuclein pathology in the brain. These data continue to demonstrate the potential of IKT-14809 as a disease modifying therapy and support the continued clinical development of IKT-148009 in Parkinson's disease.
- **Dosed first three cohorts in the '501' bioequivalence study of IKT-001Pro:** In December 2022, Inhibikase announced the dosing of the first three patients in the '501' bioequivalence study of IKT-001Pro, the Company's prodrug formulation of imatinib mesylate intended to enhance the safety and efficacy of imatinib (marketed as Gleevec®) in patients with Chronic Myelogenous Leukemia (CML). The '501' study is a single ascending dose trial and will enroll approximately 59 male and female healthy volunteers between the ages of 25 to 55 who will receive IKT-001pro at one of four single doses. Three of the four dosing cohorts in the dose escalation phase have completed the study, with the fourth escalation cohort scheduled to dose in early April 2023. The primary objective of the study is to evaluate the safety profile of IKT-001pro as well as analyze and identify a dose that mimics systemic exposure and pharmacokinetics of 400mg imatinib mesylate, the standard-of-care dose for Stable-Phase CML. The study will also evaluate the adverse event profile and patient reported outcomes as metrics of superiority over standard-of-care. Upon completion of this study, the Company intends to initiate a discussion with the FDA to discuss the parameters of drug approval under the 505(b)(2) statute.
- **Successfully completed \$10 million concurrent registered direct offering and private placement:** In January 2023, Inhibikase raised \$10 million in aggregate gross proceeds from its concurrent registered direct offering and private placement. The Company plans to use the net proceeds from the offerings for general corporate purposes, including clinical trials, product candidate development and manufacturing activities for product candidates and to meet working capital needs.

Full Year 2022 Financial Results

Grant Revenue: Grant revenue was \$0.1 million for the year ended December 31, 2022

compared to \$3.1 million in the prior year. The decrease was due to the Company's primary focus during 2022 being shifted toward advancing our Phase I and II clinical trials which were not submitted for grant revenue.

R&D Expenses: Research and development expenses were \$12.0 million for the year ended December 31, 2022 compared to \$11.4 million in the year ended December 31, 2021. The increase was primarily due to ongoing non-grant related research and development activities mostly related to the Phase 2a '201' clinical trial.

SG&A Expenses: Selling, general and administrative expenses for the year ended December 31, 2022 were \$6.2 million compared to \$6.5 million for the year ended December 31, 2021. The decrease was primarily the result of decreased warrant expense of \$0.7 million and a decrease of stock-based compensation of \$0.5 million partially offset by increased legal fees of \$0.4 million, increased regulatory and compliance fees of \$0.2 million and a net increase of \$0.3 million for other normal operating expenses.

Net Loss: Net loss for the year ended December 31, 2022 was \$18.1 million, or \$0.72 per share, compared to a net loss of \$14.8 million, or \$0.81 per share in the year ended December 31, 2021.

Cash Position: Cash, cash equivalents and marketable securities were \$23.1 million as of December 31, 2022. This excludes the net proceeds from the \$10 million January 2023 concurrent registered direct offering and private placement. The Company expects that existing cash and cash equivalents will be sufficient to fund operations into the fourth quarter of 2024.

About Inhibikase (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 has a primary focus 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 as well as other diseases that arise from Abelson Tyrosine Kinases. 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 mesylate 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 an office in Lexington, 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, including our ability to successfully conduct clinical trials, that results in our animal studies may not be replicated in humans and our ability to maintain our Nasdaq listing. Important factors that could cause actual results to differ materially from those in the forward-looking statements include factors that are delineated in our periodic reports on Form 10-K and Form 10-Q that we file with the U.S. Securities and Exchange Commission. 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.

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Inhibikase Therapeutics, Inc. Consolidated Balance Sheets

	December 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	\$ 7,188,553	\$ 40,750,133
Marketable securities	15,861,620	—
Accounts receivable	39,881	110,141
Prepaid research and development	1,117,616	107,000
Prepaid expenses and other current assets	163,452	1,502,725
Total current assets	24,371,122	42,469,999
Equipment and improvements, net	236,532	—
Right-of-use asset	328,643	—
Total assets	\$ 24,936,297	\$ 42,469,999
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 1,151,173	\$ 1,089,778
Lease obligation, current	145,836	—
Accrued expenses and other current liabilities	2,398,436	2,715,761
Notes payable	—	248,911

Total	3,695,445	4,054,450
Lease obligations, net of current portion	205,451	—
Total liabilities	3,900,896	4,054,450
Commitments and contingencies (see Note 14)		
Stockholders' equity:		
Preferred stock, \$0.001 par value; 10,000,000 shares authorized at December 31, 2022 and 2021; 0 shares issued and outstanding at December 31, 2022 and 2021	—	—
Common stock, \$0.001 par value; 100,000,000 shares authorized; 25,227,051 and 25,155,198 shares issued and outstanding at December 31, 2022 and 2021	25,227	25,155
Additional paid-in capital	68,777,298	68,208,081
Accumulated other comprehensive income	104,718	—
Accumulated deficit	(47,871,842)	(29,817,687)
Total stockholders' equity	21,035,401	38,415,549
Total liabilities and stockholders' equity	\$ 24,936,297	\$ 42,469,999

Inhibikase Therapeutics, Inc.
Consolidated Statements of Operations and Comprehensive Loss

	Year ended December 31,	
	2022	2021
Revenue:		
Grant revenue	\$ 123,440	\$ 3,100,605
Total revenue	123,440	3,100,605
Costs and expenses:		
Research and development	12,034,985	11,359,104
Selling, general and administrative	6,217,063	6,507,641
Total costs and expenses	18,252,048	17,866,745
Loss from operations	(18,128,608)	(14,766,140)
Interest income/(expense)	74,453	(19,923)
Net loss	\$ (18,054,155)	\$ (14,786,063)
Other comprehensive income, net of tax		
Unrealized gains on marketable securities	104,718	\$ —
Comprehensive loss	\$ (17,949,437)	\$ (14,786,063)
Net loss per share – basic and diluted	\$ (0.72)	\$ (0.81)
Weighted-average number of common shares – basic and diluted	25,211,726	18,209,198

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