UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): January 25, 2023

INHIBIKASE THERAPEUTICS, INC.
(Exact Name of Registrant as Specified in its Charter)

Delaware	**001-39676**	**26-3407249**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

3350 Riverwood Parkway SE, Suite 1900 **Atlanta, Georgia** **(Address of Principal Executive Offices)**	**30339** **(Zip Code)**

Registrant's Telephone Number, Including Area Code: (678) 392-3419

N/A
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (*see* General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.001 par value	IKT	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 8.01 Other Events.

On January 25, 2023, Inhibikase Therapeutics, Inc. (the "Company") issued a press release announcing that the full clinical hold on IkT-148009 in Parkinson's disease has been lifted by the U.S. Food and Drug Administration. A copy of the Company's press release regarding the lifting of the clinical hold is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

On January 25, 2023, the Company also issued a press release announcing the publication of studies describing the potential of IkT-148009 as a disease-modifying therapy for Parkinson's disease and related disorders. A copy of the Company's press release regarding the publication is attached hereto as Exhibit 99.2 and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Number	Description
99.1	Press Release dated January 25, 2023 (Clinical Hold).
99.2	Press Release dated January 25, 2023 (Publication).
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: January 25, 2023

INHIBIKASE THERAPEUTICS, INC.

By: /S/ MILTON H. WERNER
Milton H. Werner, Ph.D.
President and Chief Executive Officer

Inhibikase Therapeutics Announces FDA has Lifted the Full Clinical Hold onIkT-148009 in Parkinson's Disease

- Phase 2a '201' clinical trial will resume immediately at 50 and 100 mg doses-

-Additional safety and pharmacokinetic information will be measured in healthy subjects at the 200 mg dose prior to implementation in the 201 trial-

BOSTON and ATLANTA, January 25, 2023 — 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, Parkinson's-related disorders and other diseases of the Abelson Tyrosine Kinases, today announced the U.S. Food and Drug Administration ("FDA" or "Agency") has lifted the full Clinical Hold on IkT-148009 in Parkinson's disease (PD).

"We are grateful for the expeditious review by the FDA of our response to the Clinical Hold onIkT-148009 in PD," stated Milton H. Werner, Ph.D., President and Chief Executive Officer of Inhibikase Therapeutics. "We believe that we now have clarity on the FDA's expectations as we move forward in the 201 clinical trial for IkT-148009. We are now working tore-open clinical trial sites and initiate screening and enrollment of patients for the trial following agreed upon updates to the Protocol and Informed Consent form. We anticipate completing these restart tasks by the end of the first quarter."

IkT-148009 is a c-Abl tyrosine kinase inhibitor that has been shown to halt disease progression, protect and restore lost neurons and to clear the underlying protein pathology in animal studies that suggests a causal link to the initiation and progression of disease in humans[1]. In lifting the clinical hold, the Agency based their decision on the Company's Complete Response and Amendment dated December 21, 2022, as well as further commitments made on January 20, 2023 regarding ophthalmologic monitoring in the protocol of study IkT-148009-201 and various modifications to the Investigator Brochure. The Agency requested that the Company measure the safety and steady-state pharmacokinetic (PK) profile of the 200 mg dose in six (6) healthy subjects prior to administration of the 200 mg dose in Parkinson's patients. The 201 trial will resume at the 50 mg and 100 mg dose immediately and the safety/PK measurement at 200 mg will be performed simultaneously.

The Agency further requested the measurement of visual acuity and examination of the cornea and lens to complement the analysis of retina, macula and fundus that was already part of the ocular monitoring program in the 201 trial. This monitoring program is consistent with the monitoring program for ocular pathology of other approved protein kinase inhibitors. To date, no ocular pathology has been observed in any trial participant administered IkT-148009.

The Agency further requested removal of safety-related data in the Investigator Brochure for the primary metabolites ofIkT-148009 to give the Agency time to review the underlying report in support of this safety data.

With agreement on conditions for restart of the 201 trial and the lifting of the clinical hold onIkT-148009, the Company intends to seek a lifting of the Clinical Hold on its program focused on Multiple System Atrophy (MSA).

[1] DOI: 10.1126/scitranslmed.abp9352

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 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 as well as other diseases that arise from Ableson 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 offices in Boston, Massachusetts.

Social Media Disclaimer

Investors and others should note that the Company announces material financial information to investors using its 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 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.

Contacts:

Company Contact:
Milton H. Werner, Ph.D.
President & CEO
678-392-3419
info@inhibikase.com

Investor Relations:
Alex Lobo
SternIR, Inc.
alex.lobo@sternir.com

# # #

Inhibikase Therapeutics Announces Publication Demonstrating Potential for c-Abl as a Key Therapeutic Target in Parkinson's Disease and Related Disorders

- Animal model studies highlight potential of the c-Abl inhibitorIkT-148009 to modify the course of Parkinson's Disease and Suppress Protein Pathology -

BOSTON and ATLANTA, January 25, 2023 — 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, Parkinson's-related disorders and other diseases of the Abelson Tyrosine Kinases, today announced the publication of studies describing the potential of IkT-148009 as a disease-modifying therapy for Parkinson's disease and related disorders. The publication entitled *"The c-Abl inhibitor IkT-148009 suppresses neurodegeneration in mouse models of heritable and sporadic Parkinson's disease"* was published online in the journal *Science Translational Medicine* on January 18, 2023 (DOI: 10.1126/scitranslmed.abp9352)

"Understanding the mechanisms underlying the initiation and progression of Parkinson's disease (PD) inside and outside of the brain has remained a significant challenge to the development of disease-modifying therapeutics in PD," stated Milton H. Werner, Ph.D., President and Chief Executive Officer of Inhibikase Therapeutics. "In published work by our collaborators[1], genetic deletion of c-Abl blocked neurodegeneration in animals that exhibited alpha-synuclein aggregates or 'plaques', suggesting the essential role of c-Abl in the disease process. In this publication, we highlighted the neurodegenerative functional screen that led to the identification of IkT-148009. The publication also highlights data from once daily oral administration ofIkT-148009 in multiple animal models that mimicked the rate of disease progression found 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. The exposures toIkT-148009 used in these model studies are consistent with the exposures to IkT-148009 at a 50 mg oral dose in PD patients, one of the doses that is being evaluated in our Phase 2a '201' clinical trial in untreated Parkinson's patients. Remarkably, therapeutic benefit in these models was accompanied by substantial reduction of alpha-synuclein pathology in the brain, a long-sought goal of Parkinson's treatment. We believe that these data demonstrate the potential of IkT-14809 as a disease modifying therapy and support the continued clinical development of IkT-148009."

Key highlights included:

- Demonstration of enzyme selectivity within the c-Abl family forIkT-148009
- Implementation of a functional neurodegenerative screen enabling identification ofIkT-148009 as a potential therapeutic to suppress c-Abl activation in the brain
- Demonstration that IkT-148009 is therapeutically active as a disease-modifying treatment in animal models of PD at the same doses being evaluated in the 201 trial
- Provides clarity on how misfolded protein aggregates initiate and progress neurodegenerative diseases
- Correlates removal of protein aggregates following c-Abl inhibition by IkT-148009 with functional recovery in multiple models of human disease, a long sought goal of treatment

[1] (Brahmachari et al. Brain. 2019. PMID: 31237944)

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 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 as well as other diseases that arise from Ableson 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 offices in Boston, Massachusetts.

Social Media Disclaimer

Investors and others should note that the Company announces material financial information to investors using its 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 that results in animal studies may not be replicated in humans. 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.

Contacts:

Company Contact:
Milton H. Werner, Ph.D.
President & CEO
678-392-3419
info@inhibikase.com

Investor Relations:
Alex Lobo
SternIR, Inc.
alex.lobo@sternir.com

# # #