
**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): September 20, 2023

INHIBIKASE THERAPEUTICS, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-39676
(Commission
File Number)

26-3407249
(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 7.01 Regulation FD Disclosure.

On September 20, 2023, Inhibikase Therapeutics, Inc. (the “Company”) issued a press release containing a letter to the Company’s shareholders. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

The information contained in this Current Report on Form 8-K speaks only as of the date hereof. While the Company may elect to update the information in this Current Report on Form 8-K in the future, the Company disclaims any obligation to do so except to the extent required by applicable law.

The information furnished in this Item 7.01 of this Current Report on Form 8-K and Exhibit 99.1 attached hereto shall not be deemed “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section. The information in this Item 7.01 of this Current Report on Form 8-K is not incorporated by reference into any filings of the Company made under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date of this Current Report on Form 8-K, regardless of any general incorporation language in the filing unless specifically stated so therein.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Number	Description
99.1	Press Release dated September 20, 2023.
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: September 20, 2023

INHIBIKASE THERAPEUTICS, INC.

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



Inhibikase Therapeutics Issues a Letter to Shareholders and Comments on Recent Trading Activity

BOSTON and ATLANTA, September 20, 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 (“PD”), Parkinson’s-related disorders and other diseases of the Abelson Tyrosine Kinases, today issued a Letter to Shareholders in response to recent price volatility.

Dear Fellow Shareholders of Inhibikase Therapeutics:

We have watched, as have you, as the value of IKT has dropped dramatically in the last 8 trading sessions. Days of unusually high volume and steep declines in price have impacted the stock with no identifiable cause. We are continuing to advance our work in Parkinson’s Disease, Chronic Myelogenous Leukemia (CML) and Multiple System Atrophy (MSA), and there is no new information concerning this work that we believe could account for the volatility in share price in recent days.

Let me first address risvodetinib (IKT-148009) in Parkinson’s and related diseases. At the recent Movement Disorder Society (MDS) Congress in Copenhagen, Denmark (August 26-September 1, 2023), we presented safety and tolerability data across 119 people that reinforces our belief that risvodetinib is safe and well tolerated, and that there are no side effects of clinical significance at any dose or treatment duration measured to date. These data are presented in our corporate presentation on the Inhibikase website. At the Congress, we further detailed the changes in Parkinson’s functional assessments relative to baseline in 2-3 patients at each of the 50, 100 and 200 mg doses. These data comes from the 8 active and 3 placebo patients that had been enrolled prior to the FDA Clinical Hold placed on the 201 Trial in November, 2022. These data support the importance of the ongoing 201 Trial in untreated Parkinson’s disease that restarted with its first enrolled patient in May, 2023 following the lifting of the Clinical Hold in January of this year. Presently, 28 of the 120 planned patients are in the consenting or screening process or already enrolled in the trial. As we recently announced, one participant has already completed the 12-week dosing period and is awaiting the opportunity to participate in the planned 12 month extension study.

The implementation of our patient outreach program and launch of our patient portal (www.the201trial.com) is also providing avenues for accelerating trial enrollment. The pre-qualification questionnaire acts as a filter through which potential participants can pass and directly contact a nearby site. During September, the pre-qualification process identified an additional 50 potential participants. We believe this approach will assist all sites in concentrating their consenting and screening efforts on individuals who already meet the basic criteria for enrollment. We are encouraged by these statistics as the public awareness of the 201 Trial grows amongst the untreated Parkinson’s patient community and their caregivers and support networks.

We also presented evidence for the wider applicability of risvodetinib to other Parkinson’s-related disease at the MDS Congress, showing functional benefit in models of Multiple System Atrophy (MSA), an orphan disease that is a rapidly progressing form of Parkinsonism.

Finally, we continue to make significant progress on the path to approval of IKT-001Pro in Stable Phase Chronic Myelogenous Leukemia. IKT-001Pro is our prodrug of the anticancer agent imatinib mesylate. We have completed the necessary steps to request an FDA meeting to seek agreement on the path to approval under the 505(b)(2) regulation. Simultaneously, we continue to differentiate IKT-001Pro from standard-of-care by measuring bioequivalence to 600 mg imatinib mesylate, a dose for standard-of-care imatinib mesylate which is commonly in use, but poorly tolerated by patients. This high dose cohort is expected to be completed early in the 4th quarter of 2023.

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Collectively, we are excited by the recent accomplishments across our programs and remain on track with our stated milestones. We are continuing to work diligently to increase our Company's value and educate investors on the progress we are making. Our cash position remains sufficient to fund our operations into the fourth quarter of 2024. We appreciate the continued support of our shareholders as we seek to reconcile the disconnect between our accomplishments, the potential significance of risvodetinib as a transformative treatment for Parkinson's disease and the recent decline in the Company's market valuation.

Sincerely,

Milton H. Werner, PhD.
President & CEO

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. Important factors that could cause actual results to differ materially from those in the forward-looking statements include our ability to successfully conduct clinical trials and that results in our animal studies may not be replicated in humans, as well as such other factors that are included 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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