
**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): November 14, 2022

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 2.02 Results of Operations and Financial Condition.

On November 14, 2022, Inhibikase Therapeutics, Inc. (the “Company”) issued a press release announcing its results of operations and financial condition for the three-month period ended September 30, 2022. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information furnished pursuant to this Item 2.02, including Exhibit 99.1, shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities under that Section and shall not be deemed to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

<u>Number</u>	<u>Description</u>
99.1	<u>Press Release of Inhibikase Therapeutics, Inc. dated November 14, 2022 regarding results of operations and financial condition for the three-month period ended September 30, 2022.</u>
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: November 17, 2022

INHIBIKASE THERAPEUTICS, INC.

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



Inhibikase Therapeutics Reports Third Quarter 2022 Financial Results and Highlights Recent Period Activity

Company to host conference call and webcast on November 15, 2022 at 8:00am ET

BOSTON and ATLANTA, November 14, 2022 — 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 third quarter ended September 30, 2022 and highlighted recent developments.

“While the FDA clinical hold on our IKT-148009 programs for Parkinson’s disease and Multiple System Atrophy was unexpected, we are actively working with the agency to understand their concerns and resolve them as soon as possible. To date we have not seen any serious adverse events in our Phase 2a ‘201’ trial and believe the recently presented results from our Phase 1/1b ‘101’ trial continues to support the safety, tolerability and pharmacokinetics of IKT-148009,” commented Milton Werner, Ph.D., President and Chief Executive Officer of Inhibikase. “As we work to resolve the clinical hold, we remain on track to initiate the ‘501’ bioequivalence study to evaluate IKT-001Pro for the treatment of stable phase Chronic Myelogenous Leukemia in the fourth quarter. In addition, we will continue to gather preclinical data for IKT-148009 in MSA and expect to advance a second animal model study in the fourth quarter. We remain committed to our mission to improve the lives of patients suffering from devastating neurodegenerative diseases and look forward to providing updates as appropriate.”

Recent Developments and Upcoming Milestones:

- Phase 2a ‘201’ Clinical Trial of IKT-148009 for the Treatment of Parkinson’s Disease:** In August 2022, Inhibikase announced dosing of the first patient in its ‘201 trial’ evaluating IKT-148009 for the treatment of Parkinson’s disease. The 201 trial is a 1:1:1:1 randomized, double-blind, twelve-week dosing trial evaluating three-dose levels of IKT-148009. The primary endpoints will assess the safety, tolerability and steady-state pharmacokinetics of IKT-148009. The trial will also measure a hierarchy of fifteen Parkinson’s-related disease assessments in the brain and gut as secondary or exploratory endpoints. On November 7, 2022, Inhibikase announced that the U.S. Food and Drug Administration (“FDA”) had issued a clinical hold on the IKT-148009 development programs. The FDA indicated it will provide an official clinical hold letter to Inhibikase within 30 days to explain the reason for this action. To date, the Company has dosed eleven patients in the trial and will conduct a blinded safety assessment, but there have been no serious adverse events seen in the trial to date and only two mild adverse events have been recorded. Since none of the initial eleven patients completed the study, once the clinical hold is lifted, the study will need to be restarted.
- Presented data supporting c-Abl inhibitor therapy and the patient experience with IKT-148009 at two expert industry and academic conferences.** In September 2022, Inhibikase presented data at two scientific conferences highlighting five animal model studies of acute, inherited and sporadic disease demonstrating the functional benefit of IKT-148009 in Parkinson’s disease. At the annual Movement Disorder Society Congress in Madrid Spain, Inhibikase presented data detailing the dosing experience of healthy subjects and Parkinson’s patients from multiple doses of IKT-148009 therapy between 12.5 mg and 325 mg for up to 7 days. In addition, an assessment of Parkinson’s-related disease measures demonstrated that IKT-148009 did not worsen disease.

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At the Van Andel Institute's Grand Challenges in Parkinson's Disease conference, the Company elaborated on the fundamental studies of five distinct animal models of either acute, inherited or idiopathic disease that forms the basis of the Company's understanding of Parkinson's disease initiation and the critical role of c-Abl in the disease process. Data presented also demonstrated that treatment with IKT-148009 in animals led to functional recovery correlating with clearance of pathological alpha-synuclein protein. Clinical data presented at both conferences from the Phase 1/1b '101' trial demonstrated a favorable safety and tolerability profile up to a dose of 325 mg with no clinically significant adverse events observed.

- **Received FDA Clearance for Investigational New Drug (IND) Application for IKT-001Pro for Chronic Myelogenous Leukemia (CML):** In August 2022, Inhibikase received clearance by the FDA for its IND application for IKT-001Pro, the Company's prodrug formulation of imatinib mesylate designed to enhance the safety and efficacy of imatinib (marketed as Gleevec®). The Company is advancing IKT-001Pro into a single, ascending dose bioequivalence study for safety and efficacy evaluation of IKT-001Pro. The study will enroll approximately 56 male and female healthy volunteers between the ages of 25 and 55 who will be administered IKT-001Pro at one of three doses. In addition to safety and efficacy evaluations, the study will be designed to identify a dose that mimics the systemic exposure and pharmacokinetics of 400 mg imatinib mesylate, the standard-of-care dose for Stable-Phase CML. The Company expects to dose the first patient in its '501' bioequivalence study in the fourth quarter of 2022.
- **Appointed Gisele Dion to Board of Directors:** In September 2022, Inhibikase appointed Gisele Dion to the Board of Directors. Ms. Dion serves as chair of the Audit Committee, as well as a member of the Compensation Committee. Ms. Dion brings extensive experience in the public company space and has previously spearheaded financial, accounting and M&A strategies across large pharma.

Third Quarter 2022 Financial Results

Net Loss: Net loss for the three months ended September 30, 2022 was \$4.49 million, or \$0.18 per share, compared to a net loss of \$4.47 million, or \$0.18 per share for the comparable quarter in 2021.

Net loss for the nine months ended September 30, 2022, was \$13.78 million or \$0.55 per share, compared to a net loss of \$9.74 million, or \$0.61 per share in the comparable period in 2021.

R&D Expenses: Research and development expenses were \$2.98 million for the three months ended September 30, 2022, compared to \$3.15 million in the comparable quarter in 2021. The \$0.17 million decrease in research and development expenses for the third quarter 2022 was due to a \$0.77 million decrease in stock compensation partially offset by a net increase of \$0.60 million of all other normal R&D expenses expenditures as the Company continued to focus on and progress its PD clinical trial activities.

Research and development expenses were \$8.98 million for the nine months ended September 30, 2022 compared to \$7.97 million in comparable period in 2021. The \$1.01 million increase was driven by a \$0.49 million decrease in non-cash stock compensation expenses offset by a \$0.48 million increase in compensation and related costs, a \$0.90 million increase in external R&D services and consultants, a \$0.08 million increase in legal and a net increase of \$0.04 million in all other normal R&D expensed.

SG&A Expenses: Selling, general and administrative expenses for the three months ended September 30, 2022 were \$1.54 million compared to \$1.64 million for the comparable quarter in 2021. The decrease was primarily driven by a \$0.36 million decrease in stock compensation expense partially offset by increases of \$0.13 million and \$0.08 million of legal fees and compensation and related costs, respectively, and a \$0.04 million net increase in all other normal selling, general and administrative expenses.

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Selling, general and administrative expenses for the nine months ended September 30, 2022 were \$4.87 million compared to \$4.85 million for comparable period in 2021. The major drivers were a \$1.07 million decrease in non-cash stock compensation expense for the nine months ended September 30, 2022 compared to the nine months ended September 30, 2021. The stock compensation decrease was offset by increased compensation and related costs of \$0.38 million, increased legal fees of \$0.35 million, increased compliance, regulatory and consultants of \$0.30 million and a net increase all other normal selling, general and administrative expenses of \$0.02 million.

Cash Position: Cash, cash equivalents and marketable securities were \$26.5 million as of September 30, 2022.

Conference Call Information

The conference call is scheduled to begin at 8:00am ET on November 15, 2022. Participants should diall-844-825-9789 (United States) or 1-412-317-5180 (International) with the conference code 10172407. A live webcast may be accessed using the link [here](#), or by visiting the investors section of the Company's website at www.inhibikase.com. After the live webcast, the event will be archived on Inhibikase's website for approximately 90 days after the call.

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 offices in Lexington, 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 our ability to satisfactorily address the issues raised by the FDA in order to have the clinical hold on our IND's removed, 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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Inhibikase Therapeutics, Inc.
Condensed Consolidated Balance Sheets

	<u>September 30,</u> <u>2022</u>	<u>December 31,</u> <u>2021</u>
	<u>(unaudited)</u>	
Assets		
Current assets:		
Cash and cash equivalents	\$ 5,781,918	\$ 40,750,133
Marketable securities	20,752,290	—
Accounts receivable	13,842	110,141
Prepaid research and development	932,419	107,000
Prepaid expenses and other current assets	505,924	1,502,725
Total current assets	27,986,393	42,469,999
Equipment and improvements, net	241,574	—
Right of use asset	353,250	—
Total assets	<u>\$ 28,581,217</u>	<u>\$ 42,469,999</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 781,223	\$ 1,089,778
Lease obligation, current	142,048	—
Accrued expenses and other current liabilities	2,289,726	2,715,761
Notes payable	—	248,911
Total current liabilities	3,212,997	4,054,450
Lease obligations	232,020	—
Total liabilities	3,445,017	4,054,450
Commitments and contingencies (see Note 12)		
Stockholders' equity:		
Preferred stock, \$0.001 par value; 10,000,000 shares authorized; 0 shares issued and outstanding at September 30, 2022 and December 31, 2021	—	—
Common stock, \$0.001 par value; 100,000,000 shares authorized; 25,227,051 and 25,155,198 shares issued and outstanding at September 30, 2022 and December 31, 2021, respectively.	25,227	25,155
Additional paid-in capital	68,676,935	68,208,081
Accumulated other comprehensive income	26,828	—
Accumulated deficit	(43,592,790)	(29,817,687)
Total stockholders' equity	25,136,200	38,415,549
Total liabilities and stockholders' equity	<u>\$ 28,581,217</u>	<u>\$ 42,469,999</u>

See accompanying notes to condensed consolidated financial statements.

Inhibikase Therapeutics, Inc.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Revenue:				
Grant revenue	\$ 7,291	\$ 328,459	\$ 59,874	\$ 3,098,661
Total revenue	<u>7,291</u>	<u>328,459</u>	<u>59,874</u>	<u>3,098,661</u>
Costs and expenses:				
Research and development	2,981,653	3,154,553	8,980,827	7,968,846
Selling, general and administrative	1,538,737	1,644,946	4,872,681	4,854,494
Total costs and expenses	<u>4,520,390</u>	<u>4,799,499</u>	<u>13,853,508</u>	<u>12,823,340</u>
Loss from operations	(4,513,099)	(4,471,040)	(13,793,634)	(9,724,679)
Interest income	18,536	—	18,536	—
Interest expense	—	157	5	19,765
Net loss	<u>\$ (4,494,563)</u>	<u>\$ (4,471,197)</u>	<u>\$ (13,775,103)</u>	<u>\$ (9,744,444)</u>
Other comprehensive income:				
Unrealized gains on marketable securities	26,828	—	26,828	—
Comprehensive loss	<u>\$ (4,467,735)</u>	<u>\$ (4,471,197)</u>	<u>\$ (13,748,275)</u>	<u>\$ (9,744,444)</u>
Net loss per share – basic and diluted	<u>\$ (0.18)</u>	<u>\$ (0.18)</u>	<u>\$ (0.55)</u>	<u>\$ (0.61)</u>
Weighted-average number of common shares – basic and diluted	<u>25,227,051</u>	<u>25,143,559</u>	<u>25,219,931</u>	<u>15,868,421</u>

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