

November 14, 2023



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

**Company to host conference call on Wednesday, November 15, 2023 at 8:00 a.m. ET**

BOSTON and ATLANTA, Nov. 14, 2023 (GLOBE NEWSWIRE) -- 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, 2023 and highlighted recent developments.

"We are very pleased with the progress of the last quarter," noted Dr. Milton H. Werner, President and Chief Executive Officer of Inhibikase. "Our efforts to improve drug delivery for protein kinase inhibitors brought IKT-001Pro to pre-NDA stage just 15 months after opening of the IND. Our neurodegenerative disease programs with risvodetinib are expanding, with 20% of the Phase 2 201 Trial in untreated Parkinson's disease enrolled coupled with our efforts to initiate a Phase 2 program in Multiple System Atrophy. Finally, our internal and external medicinal chemistry programs are yielding important insights into the design of next generation Abl kinase inhibitors that could lead to a pipeline of beneficial products for Abl kinase-related diseases. Collectively, this has been a very productive period for the Company."

## **Recent Developments and Upcoming Milestones:**

- **Advancing Phase 2 '201' Trial of Risvodetinib (IKT-148009) in untreated Parkinson's disease:** As of November 10, 2023, 28 sites are open and actively evaluating prospective trial participants. Twenty-four participants have been enrolled, 7 prospective participants are in screening and 15 potential participants are going through informed consents.

The 201 Trial patient portal ([www.the201trial.com](http://www.the201trial.com)) has been visited by more than 20,000 unique people since launch in September, 2023. The pre-qualification process has led to 201 unique individuals to contact open clinical sites, the first step in the evaluation process that could lead to enrollment. Monthly site enrollments have increased month-over-month since this patient outreach program was initiated.

- **Unblinded functional analysis from the 201 Trial are encouraging:** In August 2023,

unblinded functional assessments of 11 patients with untreated Parkinson's disease were presented at the Movement Disorder Congress in Copenhagen, Denmark. These participants were withdrawn from the trial following the FDA's temporary clinical hold in November, 2022, which was lifted January, 2023. These assessments showed that patients receiving the 200 mg dose of risvodetinib (N=3) saw a greater than 10 point improvement over placebo in the sum of motor and non-motor scores after once daily treatment for up to 11 weeks; by contrast, a typical patient with Parkinson's disease would worsen by 3 to 6 points in the sum of motor and non-motor score assessments over a 12 month period. While the number of treated participants is too small for the Company to conclude a clinical benefit, these early data are cautiously encouraging.

- **Received Orphan Drug Designation in Multiple System Atrophy (MSA):** In October 2023, risvodetinib was granted Orphan Drug Designation by the FDA for the treatment of MSA. In animal model studies of MSA, risvodetinib was shown to be therapeutically active. The designation by the FDA underscores the need for innovative treatment options for patients afflicted with this rare and rapidly progressing Parkinson's-related disorder. The Company is pursuing a comparable designation in the European Union, or E.U., as part of its efforts to initiate a Phase 2 clinical trial to evaluate risvodetinib in MSA. The Company is discussing conduct of the trial with private foundations, Federal and industry stakeholders in an effort to initiate this trial in the future.
- **Completed the '501' bioequivalence studies with lKt-001Pro:** In October 2023, Inhibikase completed its bioequivalence studies of lKt-001Pro, measuring the bioequivalent dose to both 400 mg and 600 mg imatinib mesylate. The study enrolled a total of 66 healthy volunteers in three parts. In single dose studies, bioequivalent lKt-001Pro induced fewer neurological, musculoskeletal and gastrointestinal adverse events relative to 400 mg imatinib mesylate. Gastrointestinal adverse events were more persistent for imatinib mesylate in the study evaluating bioequivalence to 600 mg imatinib mesylate. Measures of bioequivalence along with safety and tolerability data are being submitted as briefing materials for a pre-NDA meeting with the FDA to reach agreement on the requirements for approval of lKt-001Pro under the 505(b)(2) statute.
- **Initiated preclinical development of second-generation c-Abl inhibitors:** In August 2023, Inhibikase initiated preclinical development of new molecules arising from internal medicinal chemistry and external collaborations identifying second generation molecules that could enhance suppression of neurodegeneration or address other diseases that could benefit from Abl kinase inhibition.

### Third Quarter Financial Results

**Net Loss:** Net loss for the three months ended September 30, 2023 was \$4.60 million, or \$0.86 per share, compared to a net loss of \$4.49 million, or \$1.06 per share in the quarter ended September 30, 2022.

**R&D Expenses:** Research and development expenses were \$3.23 million for the quarter ended September 30, 2023 compared to \$2.98 million in the quarter ended September 30, 2022. The increase was primarily due to the Company's ongoing Phase 2 '201' PD clinical trial costs.

**SG&A Expenses:** Selling, general and administrative expenses for the quarter ended September 30, 2023 were \$1.62 million compared to \$1.54 million for the quarter ended September 30, 2022. The increase was driven by net increase in normal selling, general and

administrative expenses.

**Cash Position:** Cash, cash equivalents and marketable securities were \$16.83 million as of September 30, 2023. The Company expects that existing cash and cash equivalents will be sufficient to fund operations into the fourth quarter of 2024.

### **Conference Call Information**

The conference call can be accessed by dialing 1-833-816-1414 (United States) or 1-412-317-0506 (International) with the conference code 0866324. 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](http://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](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 has a primary focus on neurodegeneration and its lead program risvodetinib, 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 risvodetinib 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 X, [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 that are statistically significant and that results from 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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## Inhibikase Therapeutics, Inc. Condensed Consolidated Balance Sheets

	September 30, 2023	December 31, 2022
	(unaudited)	(Note 3)
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 14,861,309	\$ 7,188,553
Marketable securities	1,970,260	15,861,620
Accounts receivable	—	39,881
Prepaid research and development	347,565	1,117,616
Prepaid expenses and other current assets	371,538	163,452
Total current assets	17,550,672	24,371,122
Equipment and improvements, net	79,940	236,532
Right-of-use asset	250,090	328,643
Total assets	<u>\$ 17,880,702</u>	<u>\$ 24,936,297</u>
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 734,561	\$ 1,151,173
Lease obligation, current	149,030	145,836
Accrued expenses and other current liabilities	1,858,215	2,398,436
Total current liabilities	2,741,806	3,695,445
Lease obligation, net of current portion	121,013	205,451
Total liabilities	2,862,819	3,900,896
Commitments and contingencies (see Note 13)		
Stockholders' equity:		
Preferred stock, \$0.001 par value; 10,000,000 shares authorized; 0 shares issued and outstanding at September 30, 2023 and December 31, 2022	—	—
Common stock, \$0.001 par value; 100,000,000 shares authorized; 5,360,326 and 4,224,294 shares issued and outstanding at September 30, 2023 and December 31, 2022	5,361	4,224
Additional paid-in capital	77,735,450	68,798,301
Accumulated other comprehensive income (loss)	(143)	104,718
Accumulated deficit	(62,722,785)	(47,871,842)
Total stockholders' equity	15,017,883	21,035,401
Total liabilities and stockholders' equity	<u>\$ 17,880,702</u>	<u>\$ 24,936,297</u>

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

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Revenue				
Grant revenue	\$ 79,569	\$ 7,291	\$ 260,500	\$ 59,874
Total revenue	79,569	7,291	260,500	59,874
Costs and expenses:				
Research and development	3,225,551	2,981,653	10,615,368	8,980,827
Selling, general and administrative	1,622,894	1,538,737	5,331,358	4,872,681
Total costs and expenses	4,848,445	4,520,390	15,946,726	13,853,508
Loss from operations	(4,768,876 )	(4,513,099 )	(15,686,226 )	(13,793,634 )
Interest income	173,677	18,536	835,283	18,531
Net loss	(4,595,199 )	(4,494,563 )	(14,850,943 )	(13,775,103 )
Other comprehensive income (loss), net of tax				
Unrealized gain (loss) on marketable securities	1,571	26,828	(104,861 )	26,828
Comprehensive loss	\$ (4,593,628 )	\$ (4,467,735 )	\$ (14,955,804 )	\$ (13,748,275 )
Net loss per share – basic and diluted	\$ (0.86 )	\$ (1.06 )	\$ (2.93 )	\$ (3.26 )
Weighted-average number of common shares – basic and diluted	5,342,337	4,224,294	5,060,447	4,223,099



Source: Inhibikase Therapeutics