

May 15, 2024



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

**Company to host conference call on Thursday, May 16, 2024 at 8:00 a.m. ET**

BOSTON and ATLANTA, May 15, 2024 (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 first quarter ended March 31, 2024 and highlighted recent developments.

"2024 is shaping up to be a year of clinical and regulatory execution as we advance our core programs towards important inflection points," said Dr. Milton H. Werner, President and Chief Executive Officer of Inhibikase. "The Phase 2 201 trial for Risvodetinib ("risvo") in untreated Parkinson's disease is 83% enrolled as of May 10, 2024 and we anticipate enrolling the final patient in June with biomarker and functional assessment results to be reported in the second half of the year. On the regulatory front, we had positive interactions with the FDA for IKT-001Pro in gastrointestinal and hematological cancers and cardiopulmonary disease. As we look ahead, we believe our work to date supports the continued development of both risvo and 001Pro, and we are excited to continue on this journey to bring transformative treatments for patients in need."

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

- **Completed Pre-NDA Meeting with the FDA for IKT-001Pro in oncology:** On February 12, 2024, Inhibikase received final Meeting Minutes from the FDA Review Team ("Review Team") from the Division of Hematologic Malignancies discussing the requirements for a 505(b)(2) NDA submission for IKT-001Pro in up to 11 blood and stomach cancer indications. Following receipt of the meeting minutes, the Company is considering the study of the 1200 mg dose of IKT-001Pro that is expected to lead to exposures equivalent to 800 mg imatinib as well as conduct an additional analysis comparing IKT-001Pro and imatinib mesylate in gut absorption. Inhibikase will request milestone-based meetings as it completes the necessary preclinical, clinical, manufacturing and quality control processes to ensure the Company and the Review Team remain aligned throughout the process of NDA submission.
- **Completed Pre-IND meeting with the FDA for IKT-001Pro in Pulmonary Arterial Hypertension:** On April 5, 2024, the Company met with the Office of Cardiology, Hematology, Endocrinology and Nephrology in the Division of Cardiology and

Nephrology at the FDA for a Pre-IND meeting to discuss the potential of using IKT-001Pro as a treatment for pulmonary arterial hypertension (PAH). Final Meeting Minutes were provided by the FDA on May 3, 2024 and confirmed that IKT-001Pro would be classified as a novel chemical entity and eligible for exclusivity designations even though it could be approved under the 505(b)(2) statute. The FDA supported our initial Phase 2/3 design and has requested that the Company conduct a pre-clinical hERG study in comparison to imatinib prior to submitting the IND. This cell culture-based 7-day experiment is expected to be completed in the current quarter.

- **Expect to complete enrollment for the 201 Trial of Risvodetinib in the second quarter 2024:** As of May 10, 2024, 99 participants have been enrolled, 15 prospective participants are in medical screening and 22 potential participants are being evaluated for suitability to initiate medical screening across all 32 clinical sites. 44 participants have completed the 12-week dosing period and 25 mild and 3 moderate adverse events that may have been related to risvo have been reported as of May 10, 2024. The Company expects to report topline data results in the second half of 2024, including measurement of novel biomarker data as it relates to alpha-synuclein aggregates and the effect of risvo on the underlying pathology for Parkinson's disease. Following completion of the double-blinded phase of the 201 trial, Inhibikase will request an end of Phase 2 meeting with the FDA. In addition, the Company hopes to initiate enrollment in its 12-month extension study of risvo in 2024, subject to available resources.

## First Quarter Financial Results

**Net Loss:** Net loss for the quarter ended March 31, 2024 was \$4.6 million, or \$0.73 per share, compared to a net loss of \$4.5 million, or \$0.98 per share in the quarter ended March 31, 2023.

**R&D Expenses:** Research and development expenses were \$2.8 million for the quarter ended March 31, 2024 compared to \$2.9 million in the quarter ended March 31, 2023. The \$0.1 million decrease in research and development expenses was due to a decrease of \$0.7 million in IKT-001 Pro expenses offset by a \$0.6 million increase in Risvodetinib expenses.

**SG&A Expenses:** Selling, general and administrative expenses for the quarter ended March 31, 2024 were \$2.0 million compared to \$1.9 million for the quarter ended March 31, 2023. The \$0.1 million increase was primarily driven by a \$0.18 million increase legal and consulting fees, and a \$0.08 million net decrease in all other normal selling, general and administrative expenses.

**Cash Position:** Cash, cash equivalents and marketable securities were \$9.7 million as of March 31, 2024. The Company expects that existing cash and cash equivalents will be sufficient to fund operations through November 2024.

## Conference Call Information

The conference call is scheduled to begin at 8:00am ET on May 16, 2024. Participants should dial 1-877-407-0789 (United States) or 1-201-689-8562 (International). 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 several follow-on compounds to Risvodetinib that could potentially be 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 [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 enroll and complete the 201 Trial evaluating Risvodetinib in untreated Parkinson's disease, to successfully apply for and obtain FDA approval for IKT-001Pro in blood and stomach cancers or other indications, to successfully conduct clinical trials that are statistically significant and whether results from our animal studies may 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**

	<u>March 31, 2024</u>	<u>December 31, 2023</u>
	(unaudited)	(Note 2)
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 2,353,346	\$ 9,165,179
Marketable securities	7,396,009	4,086,873
Accounts receivable	-	-
Prepaid research and development	207,422	219,817
Prepaid expenses and other current assets	851,057	739,179
Total current assets	<u>10,807,834</u>	<u>14,211,048</u>
Equipment and improvements, net	66,804	73,372
Right-of-use asset	193,460	222,227
Total assets	<u>\$ 11,068,098</u>	<u>\$ 14,506,647</u>
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 1,293,755	\$ 646,767
Lease obligation, current	151,159	150,095
Accrued expenses and other current liabilities	2,507,589	2,259,955
Insurance premium financing payable	280,614	381,784
Total current liabilities	<u>4,233,117</u>	<u>3,438,601</u>
Lease obligation, net of current portion	58,330	90,124
Total liabilities	<u>4,291,447</u>	<u>3,528,725</u>
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 March 31, 2024 and December 31, 2023	—	—
Common stock, \$0.001 par value; 100,000,000 shares authorized; 6,476,844 and 6,186,280 shares issued and outstanding at March 31, 2024 and December 31, 2023	6,477	6,186
Additional paid-in capital	78,322,334	77,871,584
Accumulated other comprehensive (loss) income	(1,800)	877
Accumulated deficit	<u>(71,550,360)</u>	<u>(66,900,725)</u>
Total stockholders' equity	<u>6,776,651</u>	<u>10,977,922</u>
Total liabilities and stockholders' equity	<u>\$ 11,068,098</u>	<u>\$ 14,506,647</u>

See accompanying notes to condensed consolidated financial statements.

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

	<u>Three Months Ended March 31,</u>	
	<u>2024</u>	<u>2023</u>
Revenue:		
Grant revenue	\$ —	\$ 64,521
Total revenue	<u>—</u>	<u>64,521</u>

Costs and expenses:		
Research and development	2,751,279	2,854,119
Selling, general and administrative	2,031,081	1,925,351
Total costs and expenses	<u>4,782,360</u>	<u>4,779,470</u>
Loss from operations	(4,782,360)	(4,714,949)
Interest income	132,725	237,171
Net loss	<u>(4,649,635)</u>	<u>(4,477,778)</u>
Other comprehensive income (loss), net of tax		
Unrealized (loss) gains on marketable securities	(2,677)	61,104
Comprehensive loss	<u>\$ (4,652,312)</u>	<u>\$ (4,416,674)</u>
Net loss per share – basic and diluted	<u>\$ (0.73)</u>	<u>\$ (0.98)</u>
Weighted-average number of common shares – basic and diluted	<u>6,340,697</u>	<u>4,585,013</u>

See accompanying notes to condensed consolidated financial statements.



Source: Inhibikase Therapeutics