

August 14, 2024



Inhibikase Therapeutics Reports Second Quarter Financial Results and Highlights Recent Period Activity

Company to host conference call on August 15, 2024 at 8:00 a.m. ET

BOSTON and ATLANTA, Aug. 14, 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 second quarter ended June 30, 2024 and highlighted recent developments.

"The first half of 2024 has showcased the strength of our pipeline through the continued execution of key milestones for both risvodetinib (risvo) and IkT-001Pro," said Dr. Milton H. Werner, President and Chief Executive Officer of Inhibikase. "We completed enrollment of The 201 Trial evaluating risvo in untreated Parkinson's disease, and anticipate the last patient exiting the study in September, 2024. We anticipate reporting topline data in November, 2024. Additionally, 001Pro has advanced as a potential treatment for Pulmonary Arterial Hypertension (PAH). We have filed our IND and we intend to ramp up the 702 trial following IND clearance. Finally, the manufacturing requirements for 001Pro necessary for potential approval is advancing with the on-going development of a scalable process."

Recent Developments and Upcoming Milestones:

- **Completed enrollment of the Phase 2 '201' trial evaluating risvodetinib in untreated Parkinson's disease:** On June 17, 2024, Inhibikase announced that the final participant had been enrolled in The 201 Trial evaluating the safety and tolerability of risvodetinib as a treatment in untreated Parkinson's patients. The trial has enrolled and randomized 126 patients total. The last patient will exit the trial in September, 2024. As of July 29, 2024, 84 participants have completed the 12-week dosing period. There have been 41 mild and 8 moderate adverse events observed that may be related to risvo treatment. Six people withdrew from the trial without completing 12 weeks of treatment. Forty-six people have agreed to participate in biomarker studies of the change in synuclein aggregate deposition in the skin and seven have agreed to biomarker studies of the status of synuclein aggregate in the spinal fluid.
- **Expanded Pipeline with advancement of IkT-001Pro as a therapy in Pulmonary Arterial Hypertension:** Following receipt of final meeting minutes from Inhibikase's pre-IND meeting with the FDA in May 2024, the Company submitted its IND to the FDA and plans to begin ramp-up of the Phase 2 702 trial to evaluate IkT-001Pro as a

treatment for PAH, subject to receipt of the Study May Proceed letter from the FDA. In the final meeting minutes, the FDA stated that Inhibikase had built a bridge between imatinib's use in blood and gastrointestinal cancers and PAH and that the Company's Phase 2 design, to be known as the 702 trial, was reasonable. The Company has completed the requested pre-clinical hERG safety study showing that IKT-001Pro does not inhibit hERG and therefore is unlikely to induce QTcF prolongation in treated patients. Imatinib has previously been shown to induce QTcF prolongation in some patients.

The active ingredient in IKT-001Pro, imatinib, has previously been shown to be disease-modifying for PAH. The Company believes that 001Pro could have a more favorable safety and tolerability profile compared to imatinib for this indication. If approved, IKT-001Pro could be a branded product with all the value drivers of a novel treatment for an indication with high unmet need valued at \$7.66 billion in 2023 according to global sales data from Evaluate Pharma.

- **Scaled manufacturing of IKT-001Pro:** Following the Company's pre-NDA meeting with the U.S. FDA in January 2024, Inhibikase scaled its process development efforts for IKT-001Pro to support late-stage clinical development and NDA batch requirements. Ongoing activities include development of new dosage forms, a more efficient production process and a high throughput tableting process that will lead to dosage forms for 001Pro tablets that are differentiated from generic imatinib mesylate in alignment with FDA feedback.
- **Successfully raised \$4.0 Million in a registered direct offering and concurrent private placement:** In May 2024, Inhibikase raised \$4 million in aggregate gross proceeds from its registered direct offering and concurrent private placement. The Company is using the net proceeds from the offering to progress risvodeetinib towards its planned Phase 3 trials in 2025 and completed pre-clinical studies requested by the FDA that enabled the IND filing for 001Pro in PAH.

Second Quarter Financial Results

Net Loss: Net loss for the quarter ended June 30, 2024, was \$5.0 million, or \$0.66 per share, compared to a net loss of \$5.8 million, or \$0.94 per share in the quarter ended June 30, 2023. The net loss per share for the three and six months ended June 30, 2023, was adjusted to show an improvement from (\$1.11) to (\$0.94) and from (\$2.09) to (\$1.74), respectively.

R&D Expenses: Research and development expenses were \$3.1 million for the quarter ended June 30, 2024 compared to \$4.5 million in the quarter ended June 30, 2023. The \$1.5 million decrease in research and development expenses was due to a decrease of \$1.4 million in IKT-001Pro expenses due to the completion of the three-part dose finding/dose equivalence study in 2023 and a net decrease of \$0.1 million in other research and development expenses.

SG&A Expenses: Selling, general and administrative expenses for the quarter ended June 30, 2024 were \$2.0 million compared to \$1.8 million for the quarter ended June 30, 2023. The \$0.2 million increase was primarily driven by a \$0.4 million increase legal and consulting fees partially offset by a \$0.1 million decrease in D&O insurance and a \$0.1 million net decrease in all other normal selling, general and administrative expenses.

Cash Position: Cash, cash equivalents and marketable securities were \$7.9 million as of

June 30, 2024. The Company expects that existing cash and cash equivalents will be sufficient to fund operations into December, 2024.

Conference Call Information

The conference call is scheduled to begin at 8:00am ET on August 15, 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. 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 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 for the treatment of certain hematological or gastrointestinal cancers and in cardiopulmonary disease. 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 (Unaudited)

	June 30, 2024 (unaudited)	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	\$ 3,086,455	\$ 9,165,179
Marketable securities	4,853,559	4,086,873
Prepaid research and development	306,300	219,817
Prepaid expenses and other current assets	356,487	739,179
Total current assets	8,602,801	14,211,048
Equipment and improvements, net	60,235	73,372
Right-of-use asset	163,762	222,227
Total assets	<u>\$ 8,826,798</u>	<u>\$ 14,506,647</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 1,340,538	\$ 646,767
Lease obligation, current	152,224	150,095
Accrued expenses and other current liabilities	2,034,525	2,259,955
Insurance premium financing payable	177,256	381,784
Total current liabilities	3,704,543	3,438,601
Lease obligation, net of current portion	25,606	90,124
Total liabilities	<u>3,730,149</u>	<u>3,528,725</u>
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.001 par value; 10,000,000 shares authorized; 0 shares issued and outstanding at June 30, 2024 and December 31, 2023	—	—
Common stock, \$0.001 par value; 100,000,000 shares authorized; 7,216,145 and 6,186,280 shares issued and outstanding at June 30, 2024 and December 31, 2023	7,216	6,186
Additional paid-in capital	81,600,425	77,871,584
Accumulated other comprehensive (loss) income	(1,024)	877
Accumulated deficit	<u>(76,509,968)</u>	<u>(66,900,725)</u>

Total stockholders' equity	5,096,649	10,977,922
Total liabilities and stockholders' equity	\$ 8,826,798	\$ 14,506,647

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Revenue:				
Grant revenue	\$ —	\$ 116,410	\$ —	\$ 180,931
Total revenue	—	116,410	—	180,931
Costs and expenses:				
Research and development	3,075,830	4,535,698	5,827,109	7,389,817
Selling, general and administrative	1,974,705	1,783,113	4,005,786	3,708,464
Total costs and expenses	5,050,535	6,318,811	9,832,895	11,098,281
Loss from operations	(5,050,535)	(6,202,401)	(9,832,895)	(10,917,350)
Interest income (expense)	90,927	424,435	223,652	661,606
Net loss	(4,959,608)	(5,777,966)	(9,609,243)	(10,255,744)
Other comprehensive income, net of tax				
Unrealized (loss) gains on marketable securities	776	(167,536)	(1,901)	(106,432)
Comprehensive Loss	\$ (4,958,832)	\$ (5,945,502)	\$ (9,611,144)	\$ (10,362,176)
Net loss per share – basic and diluted	\$ (0.66)	\$ (0.94)	\$ (1.38)	\$ (1.74)
Weighted-average number of common shares – basic and diluted	7,535,667	6,162,280	6,939,779	5,883,895



Source: Inhibikase Therapeutics