March 27, 2024

Inhibikase Therapeutics Reports Fourth Quarter and Full Year 2023 Financial Results and Highlights Recent Activity

Company to host conference call on Thursday, March 28, 2024 at 8:00 a.m. ET

BOSTON and ATLANTA, March 27, 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 fourth quarter and full year ended December 31, 2023 and highlighted recent developments.

"2023 was a year of clinical execution across our pipeline, culminating in the recent pre-NDA meeting with the FDA for IkT-001Pro and robust enrollment of untreated Parkinson's patients in our 201 Trial evaluating Risvodetinib ("Risvo")," said Dr. Milton H. Werner, President and Chief Executive Officer of Inhibikase. "As we look ahead, we believe that FDA feedback from our pre-NDA meeting was constructive as we work on the requirements for NDA submission for IkT-001Pro. In addition, enrollment of patients into the 201 Trial supports our belief that topline data from the three-month, double-blind phase of the study may be available in the second half of this year. Our recent publication of Phase 1 safety, tolerability and pharmacokinetic clinical data for Risvo in the *Journal of Parkinson's Disease* reinforces our belief that Risvo is well tolerated and reaches therapeutic exposures in patients with Parkinson's disease and related disorders. We look forward to taking advantage of the recent momentum we have experienced as we continue to build value for our shareholders and bring new medicines to patients in need."

Recent Developments and Upcoming Milestones:

- **Completed Pre-NDA Meeting with the FDA for IkT-001Pro:** On January 19, 2024, Inhibikase met with the FDA Review Team ("Review Team") from the Division of Hematologic Malignancies to discuss requirements for a 505(b)(2) NDA submission for IkT-001Pro in up to 11 blood and stomach cancer indications. Final Meeting Minutes were provided by the FDA on February 12, 2024. The Meeting Minutes confirmed that the 505(b)(2) pathway appears to be appropriate for approval of IkT-001Pro. The Review Team removed the requirement to perform a formal use-related risk assessment but expects the NDA package to justify how medication errors will be avoided for physicians, pharmacists and patients who are prescribed IkT-001Pro. The Company plans to manufacture dosage forms at 150 mg and 300 mg to discriminate

IkT-001Pro from the 100 mg and 400 mg dosage forms of imatinib mesylate. These alternative dosage forms do not require any manufacturing process development. In terms of bioequivalence, clinical studies completed to date indicate that imatinib delivered by 600 mg and 800 mg IkT-001Pro provide similar exposures to imatinib delivered by 400 mg and 600 mg imatinib mesylate, respectively. Imatinib mesylate is approved for use between 300 mg and 800 mg once daily for 11 blood or stomach cancers. To cover the range of approved doses of imatinib mesylate, the Company plans to study the 1200 mg dose of IkT-001Pro that is expected to lead to exposures equivalent to 800 mg imatinib. The Review Team also suggested the Company analyze how IkT-001Pro and imatinib mesylate behave with respect to certain gut transporters that regulate absorption from the gastrointestinal tract. Inhibikase is in alignment with the FDA on this point and is initiating the necessary pre-clinical test to compare IkT-001Pro and imatinib mesylate. The Review Team and Company also agreed on the size of drug substance and drug product batches needed to meet the quality control requirements for approval. The Company will request milestone-based meetings as it completes the manufacturing and quality control processes to ensure the Company and the Review Team remain aligned throughout the process. The Company also continues to evaluate the market potential of IkT-001Pro in non-oncology indications to which imatinib has already been shown to have clinical benefit.

- **Actively enrolling patients in the Phase 2 201 Trial of Risvodetinib (IkT-148009) in untreated Parkinson's disease:** As of March 22, 2024, 73 participants have been enrolled, 20 prospective participants are in medical screening and 48 potential participants are being evaluated for suitability to initiate medical screening. Additionally, 34 participants have completed the 12-week dosing period. 15 mild and 2 moderate adverse events that may have been related to Risvo have been reported thus far in the trial. As the trial remains blinded, it is unknown whether any or how many of these mild or moderate adverse events are actually related to Risvo itself. Depending on the enrollment of the last participant, the Company may report topline results from the 201 Trial in the second half of 2024, including measurement of novel biomarker data as it relates to alpha-synuclein aggregates.

- **Published Phase 1 Results of Risvodetinib in the*Journal of Parkinson's Disease:*** In January 2024, Inhibikase published the results of its Phase 1 clinical studies with Risvo entitled "*A Phase I, Randomized, SAD, MAD, and PK Study of Risvodetinib in Older Adults and Parkinson's Disease,"* online in the peer reviewed *Journal of Parkinson's Disease.* The publication highlighted data demonstrating that Risvo was well tolerated up to 7 days of daily dosing with no clinically meaningful events in healthy volunteers or worsening of symptoms in participants taking anti-PD medications. Of note, voluntary lumbar puncture was used to measure the concentration of Risvo in cerebrospinal fluid (CSF) in six participants with or without PD. Measures of the CSF concentration of Risvo indicate that it crossed the blood-brain barrier and was persistently present in the central nervous system.

Full Year 2023 Financial Results

Net Loss: Net loss for the year ended December 31, 2023, was $19.0 million, or $3.57 per share, compared to a net loss of $18.1 million, or $4.28 per share for the year ended December 31, 2022.

R&D Expenses: Research and development expenses for the year ended December 31, 2023 were $13.6 million compared to $12.0 million for the full year 2022. The $1.6 million increase was primarily due to a $1.5 million increase in CML expenditures, a decrease of $0.6 million in PD expenses and a net increase of $0.7 million in all other research and development activities.

SG&A Expenses: Selling, general and administrative expenses for the year ended December 31, 2023 were $6.7 million compared to $6.2 million for the year ended December 31, 2022. The $0.5 million increase was primarily the result of an increase in investor relations costs of $1.0 million and an increase in employee costs of $0.3 million that were partly offset by a decrease in D&O insurance of $0.6 million, a decrease in legal and consulting fees of $0.4 million and a net increase of $0.2 million in all other selling, general and administrative expenses.

Cash Position: Cash, cash equivalents and marketable securities were $13.3 million as of December 31, 2023. The Company expects that existing cash and cash equivalents will be sufficient to fund operations into the first quarter of 2025.

Conference Call Information

Inhibikase will host a conference call and webcast to discuss its full-year 2023 financial results and business highlights tomorrow, March 28, 2024, at 8:00am ET. The conference call can be accessed by dialing 1-877-407-0789 (United States) or 1-201-689-8562 (International) and referencing Inhibikase Therapeutics. 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. 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.
Consolidated Balance Sheets

	December 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 9,165,179	$ 7,188,553
Marketable securities	4,086,873	15,861,620
Accounts receivable	-	39,881
Prepaid research and development	219,817	1,117,616
Prepaid expenses and other current assets	739,179	163,452
Total current assets	14,211,048	24,371,122
Equipment and improvements, net	73,372	236,532
Right-of-use asset	222,227	328,643
Total assets	$ 14,506,647	$ 24,936,297
Liabilities and stockholders' equity		

Current liabilities:		
Accounts payable	$ 646,767	$ 1,151,173
Lease obligation, current	150,095	145,836
Accrued expenses and other current liabilities	2,259,955	2,398,436
Insurance premium financing payable	381,784	—
Total current liabilities	3,438,601	3,695,445
Lease obligations, net of current portion	90,124	205,451
Total liabilities	3,528,725	3,900,896
Commitments and contingencies (see Note 14)		
Stockholders' equity:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized at December 31, 2023 and 2022; 0 shares issued and outstanding at December 31, 2023 and 2022	—	—
Common stock, $0.001 par value; 100,000,000 shares authorized; 6,186,280 and 4,224,294 shares issued and outstanding at December 31, 2023 and 2022	6,186	4,224
Additional paid-in capital	77,871,584	68,798,301
Accumulated other comprehensive income	877	104,718
Accumulated deficit	(66,900,725)	(47,871,842)
Total stockholders' equity	10,977,922	21,035,401
Total liabilities and stockholders' equity	$ 14,506,647	$ 24,936,297

See accompanying notes to consolidated financial statements.

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

	Year ended December 31,	
	2023	**2022**
Revenue:		
Grant revenue	$ 260,501	$ 123,440
Total revenue	260,501	123,440
Costs and expenses:		
Research and development	13,618,348	12,034,985
Selling, general and administrative	6,731,945	6,217,063
Total costs and expenses	20,350,293	18,252,048
Loss from operations	(20,089,792)	(18,128,608)
Interest income	1,060,909	74,453
Net loss	(19,028,883)	(18,054,155)
Other comprehensive income, net of tax:		
Unrealized gains (losses) on marketable securities	(103,841)	104,718
Comprehensive loss	$ (19,132,724)	$ (17,949,437)
Net loss per share – basic and diluted	$ (3.57)	$ (4.28)
Weighted-average number of common shares – basic and diluted	5,333,096	4,223,099

See accompanying notes to consolidated financial statements.

Source: Inhibikase Therapeutics