UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended September 30, 2024

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to

Commission File Number: 001-39676

INHIBIKASE THERAPEUTICS, INC.
(Exact Name of Registrant as Specified in its Charter)

Delaware	**26-3407249**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
3350 Riverwood Parkway SE, Suite 1900 Atlanta, GA	**30339**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (678) 392-3419

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 (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		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. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of November 1, 2024, the registrant had 67,192,570 shares of common stock, $0.001 par value per share, outstanding.

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PART I—FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements (Unaudited).

Inhibikase Therapeutics, Inc.
Condensed Consolidated Balance Sheets

	September 30, 2024 (unaudited)	December 31, 2023 (Note 3)
Assets		
Current assets:		
Cash and cash equivalents	$ 913,420	$ 9,165,179
Marketable securities	2,330,226	4,086,873
Prepaid research and development	112,225	219,817
Deferred offering costs	553,318	147,445
Prepaid expenses and other current assets	280,914	591,734
Total current assets	4,190,103	14,211,048
Equipment and improvements, net	53,667	73,372
Right-of-use asset	133,105	222,227
Total assets	$ 4,376,875	$ 14,506,647
Liabilities and stockholders' (deficit) equity		
Current liabilities:		
Accounts payable	$ 2,529,220	$ 646,767
Lease obligation, current	145,210	150,095
Accrued expenses and other current liabilities	2,161,374	2,259,955
Insurance premium financing payable	71,662	381,784
Total current liabilities	4,907,466	3,438,601
Lease obligation, net of current portion	—	90,124
Total liabilities	4,907,466	3,528,725
Commitments and contingencies (see Note 13)		
Stockholders' (deficit) equity:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized; 0 shares issued and outstanding at September 30, 2024 and December 31, 2023	—	—
Common stock, $0.001 par value; 100,000,000 shares authorized; 7,464,070 and 6,186,280 shares issued and outstanding at September 30, 2024 and December 31, 2023	7,464	6,186
Additional paid-in capital	81,748,225	77,871,584
Accumulated other comprehensive income	1,754	877
Accumulated deficit	(82,288,034)	(66,900,725)
Total stockholders' (deficit) equity	(530,591)	10,977,922
Total liabilities and stockholders' (deficit) equity	$ 4,376,875	$ 14,506,647

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,	
	2024	2023	2024	2023
Revenue:				
Grant revenue	$ —	$ 79,569	$ —	$ 260,500
Total revenue	—	79,569	—	260,500
Costs and expenses:				
Research and development	4,189,873	3,225,551	10,016,982	10,615,368
Selling, general and administrative	1,637,603	1,622,894	5,643,386	5,331,358
Total costs and expenses	5,827,476	4,848,445	15,660,368	15,946,726
Loss from operations	(5,827,476)	(4,768,876)	(15,660,368)	(15,686,226)
Interest income	49,410	173,677	273,059	835,283
Net loss	(5,778,066)	(4,595,199)	(15,387,309)	(14,850,943)
Other comprehensive income (loss), net of tax				
Unrealized gains (loss) on marketable securities	2,778	1,571	877	(104,861)
Comprehensive loss	$ (5,775,288)	$ (4,593,628)	$ (15,386,432)	$ (14,955,804)
Net loss per share – basic and diluted	$ (0.65)	$ (0.75)	$ (2.03)	$ (2.48)
Weighted-average number of common shares – basic and diluted	8,882,570	6,162,671	7,592,103	5,977,841

See accompanying notes to condensed consolidated financial statements.

Inhibikase Therapeutics, Inc.
Condensed Consolidated Statements of Stockholders' Equity (Deficit)
(Unaudited)

	Common Stock					
	Shares	Amount	Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity (Deficit)
Balance at December 31, 2023	6,186,280	$ 6,186	$ 77,871,584	$ 877	$ (66,900,725)	$ 10,977,922
Stock-based compensation expense	—	—	53,434	—	—	53,434
Issuance of common stock, pre-funded warrants and warrants, net of issuance costs	290,564	291	397,316	—	—	397,607
Other comprehensive loss	—	—	—	(2,677)	—	(2,677)
Net loss	—	—	—	—	(4,649,635)	(4,649,635)
Balance at March 31, 2024	6,476,844	6,477	78,322,334	(1,800)	(71,550,360)	6,776,651
Stock-based compensation expense	—	—	30,697	—	—	30,697
Issuance of common stock, pre-funded warrants and warrants, net of issuance costs	739,301	739	3,247,394	—	—	3,248,133
Other comprehensive income	—	—	—	776	—	776
Net loss	—	—	—	—	(4,959,608)	(4,959,608)
Balance at June 30, 2024	7,216,145	7,216	81,600,425	(1,024)	(76,509,968)	5,096,649
Stock-based compensation expense	—	—	148,024	—	—	148,024
Issuance of common stock, stock options exercised	247,925	248	(224)	—	—	24
Other comprehensive income	—	—	—	2,778	—	2,778
Net loss	—	—	—	—	(5,778,066)	(5,778,066)
Balance at September 30, 2024	7,464,070	$ 7,464	$ 81,748,225	$ 1,754	$ (82,288,034)	$ (530,591)

Inhibikase Therapeutics, Inc.
Condensed Consolidated Statements of Stockholders' Equity
(Unaudited)

	Common Stock					
	Shares	Amount	Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
Balance at December 31, 2022	4,224,294	$ 4,224	$ 68,798,301	$ 104,718	$ (47,871,842)	$ 21,035,401
Stock-based compensation expense	—	—	123,273	—	—	123,273
Issuance of common stock, pre-funded warrants and warrants, net of issuance costs	971,532	972	8,541,970	—	—	8,542,942
Other comprehensive income	—	—	—	61,104	—	61,104
Net loss	—	—	—	—	(4,477,778)	(4,477,778)
Balance at March 31, 2023	5,195,826	5,196	77,463,544	165,822	(52,349,620)	25,284,942
Stock-based compensation expense	—	—	124,845	—	—	124,845
Issuance of common stock, pre-funded warrants and warrants, net of issuance costs	95,000	95	—	—	—	95
Other comprehensive loss	—	—	—	(167,536)	—	(167,536)
Net loss	—	—	—	—	(5,777,966)	(5,777,966)
Balance at June 30, 2023	5,290,826	5,291	77,588,389	(1,714)	(58,127,586)	19,464,380
Stock-based compensation expense	—	—	129,781	—	—	129,781
Issuance of common stock, pre-funded warrants and warrants, net of issuance costs	69,500	70	17,280	—	—	17,350
Other comprehensive income	—	—	—	1,571	—	1,571
Net loss	—	—	—	—	(4,595,199)	(4,595,199)
Balance at September 30, 2023	5,360,326	$ 5,361	$ 77,735,450	$ (143)	$ (62,722,785)	$ 15,017,883

See accompanying notes to condensed consolidated financial statements.

Inhibikase Therapeutics, Inc.
Condensed Consolidated Statements of Cash Flows
(Unaudited)

	Nine Months Ended September 30,	
	2024	**2023**
Cash flows from operating activities		
Net loss	$ (15,387,309)	$ (14,850,943)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	19,705	170,830
Stock-based compensation expense	232,155	377,899
Non-cash consulting and marketing fees	—	17,280
Changes in operating assets and liabilities:		
Accounts receivable	—	39,881
Operating lease right-of-use assets	89,122	78,553
Prepaid expenses and other assets	698	(208,086)
Prepaid research and development	107,592	770,051
Accounts payable	1,329,135	(416,612)
Operating lease liabilities	(95,009)	(81,244)
Accrued expenses and other current liabilities	(98,581)	(540,221)
Net cash used in operating activities	(13,802,492)	(14,642,612)
Cash flows from investing activities		
Purchases of equipment and improvements	—	(14,238)
Purchases of investments - marketable securities	(10,343,939)	(20,629,391)
Maturities of investments - marketable securities	12,101,463	34,415,890
Net cash provided by investing activities	1,757,524	13,772,261
Cash flows from financing activities		
Proceeds from issuance of common stock, pre-funded warrants and warrants, net of issuance costs	3,793,209	8,543,107
Net cash provided by financing activities	3,793,209	8,543,107
Net (decrease) increase in cash and cash equivalents	(8,251,759)	7,672,756
Cash and cash equivalents at beginning of period	9,165,179	7,188,553
Cash and cash equivalents at end of period	$ 913,420	$ 14,861,309
Supplement disclosure of non-cash financing activities		
Non-cash financing costs included in accounts payable	$ 553,318	$ —
Supplemental disclosures of cash flow information		
Issuance costs	$ 1,203,350	$ 1,456,479

See accompanying notes to condensed consolidated financial statements.

1.Nature of Business

We are a clinical-stage pharmaceutical company developing protein kinase inhibitor therapeutics to modify the course of cardiopulmonary and neurodegenerative diseases and other diseases that arise from aberrant signaling through the Abelson Tyrosine Kinases. The Company's multi-therapeutic pipeline includes IkT-001Pro, a prodrug of the anticancer agent imatinib, for the treatment of Pulmonary Arterial Hypertension and risvodetinib (also known as IkT-148009), a selective inhibitor of the non-receptor Abelson Tyrosine Kinases which could be disease-modifying for Parkinson's disease. Risvodetinib has completed a Phase 2, double-blind placebo-controlled trial evaluating three doses of risvodetinib 1:1:1:1 randomized against placebo. IkT-001Pro has completed bioequivalence dose calibration studies to determine the dose of IkT-001Pro that is equivalent to either 400 mg or 600 mg imatinib mesylate in preparation for a future late-stage trial in Pulmonary Arterial Hypertension (PAH).

2. Liquidity

As at September 30, 2024, the Company had cash and cash equivalents of $913,420 and marketable securities of $2,330,226, which does not include the gross proceeds of approximately $110 million from the October 2024 Offering. See Note 14, *Subsequent Event*.

The Company has incurred recurring losses and at September 30, 2024, had an accumulated deficit of $82,288,034.

The future success of the Company is dependent on its ability to successfully obtain additional working capital, obtain regulatory approval for and successfully launch and commercialize its product candidates and to ultimately attain profitable operations.

The Company is subject to a variety of risks similar to other early-stage life science companies including, but not limited to, the successful development, regulatory approval, and market acceptance of the Company's product candidates, development by its competitors of new technological innovations, protection of proprietary technology, and raising additional working capital. The Company has incurred significant research and development expenses, general and administrative expenses related to its product candidate programs and negative cash flows from operations. The Company anticipates costs and expenses to increase in the future as the Company continues to develop its product candidates.

The Company may seek to fund its operations, particularly with respect to its neurodegenerative disease programs, through additional public equity, private equity, or debt financings, as well as other sources. However, the Company may be unable to raise additional working capital, or if it is able to raise additional capital, it may be unable to do so on commercially favorable terms. The Company's failure to raise capital or enter into such other arrangements if and when needed would have a negative impact on the Company's business, results of operations and financial condition and the Company's ability to continue to develop its product candidates.

The Company estimates that its cash and cash equivalents and marketable securities at September 30, 2024, including the $110 million of gross proceeds from the October 2024 Offering, is sufficient to fund its normal operations for at least the next twelve months.

The accompanying condensed consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the ordinary course of business. The condensed consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of the uncertainties described above.

3.Basis of Presentation and Significant Accounting Policies

Basis of Presentation of Interim Financial Statements

The accompanying unaudited condensed consolidated financial statements were prepared by the Company pursuant to the rules and regulations of the Securities and Exchange Commission (the "SEC") for interim financial statements and, in the opinion of management, include all normal and recurring adjustments necessary to present fairly the results of the interim periods shown. The December 31, 2023 balance sheet was derived from the December 31, 2023 audited financial statements. Certain information and footnote disclosures normally included in financial statements prepared in accordance with U.S. generally accepted accounting principles ("US GAAP") have been condensed or omitted pursuant to such SEC rules and regulations. Management believes that the disclosures made are adequate to make the information presented not misleading. The results for the interim periods are not necessarily indicative of results to be expected for the fiscal year ending December 31, 2024. The unaudited condensed consolidated

financial statements contained herein should be read in conjunction with the Company's annual audited financial statements and notes thereto for the year ended December 31, 2023 included in the Company's Annual Report on Form 10-K filed with the SEC.

The unaudited condensed consolidated financial statements have been prepared in conformity with US GAAP, which prescribes elimination of all significant intercompany accounts and transactions in the accounts of the Company and its wholly-owned subsidiary, IKT Securities Corporation, Inc., which was incorporated in the Commonwealth of Massachusetts in December 2021. Any reference in these notes to applicable guidance is meant to refer to the authoritative US GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Update ("ASU") of the Financial Accounting Standards Board ("FASB").

From time to time, new accounting pronouncements are issued by the FASB or other standard setting bodies and are generally adopted by the Company as of the specified effective date. Unless otherwise discussed, the Company believes that the impact of recently issued standards that are not yet effective will not have a material impact on its financial position or results of operations upon adoption.

The Company qualifies as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, as amended, or the JOBS Act. The JOBS Act permits an emerging growth company such as the Company to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies until those standards would otherwise apply to private companies. The Company has elected not to "opt out" of such extended transition period, which means that when a standard is issued or revised and it has different application dates for public or private companies, the Company will adopt the new or revised standard at the time private companies adopt the new or revised standard and will do so until such time that it either (i) irrevocably elects to "opt out" of such extended transition period or (ii) no longer qualifies as an emerging growth company.

Use of Estimates

The preparation of the Company's financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. The Company utilizes certain estimates in the determination of our liquidity and working capital adequacy, the fair value of its stock options and warrants, deferred tax valuation allowances and revenue recognition, to record expenses relating to research and development contracts and accrued expenses. The Company bases its estimates on historical experience and other market-specific or other relevant assumptions that it believes to be reasonable under the circumstances. Actual results could differ from such estimates.

New Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the FASB or other standard setting bodies that the Company adopts as of the specified effective date. Unless otherwise discussed below, the Company does not believe that the adoption of recently issued standards have or may have a material impact on its condensed consolidated financial statements and disclosures.

In November 2023, the FASB issued Accounting Standards Update No. 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures which is intended to improve reportable segment disclosure requirements, primarily through enhanced disclosures about significant segment expenses. The new guidance is effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024, and early adoption is permitted. The guidance is to be applied retrospectively to all prior periods presented in the financial statements. Upon transition, the segment expense categories and amounts disclosed in the prior periods should be based on the significant segment expense categories identified and disclosed in the period of adoption. The Company is currently evaluating the potential impact of adopting this new guidance on our consolidated financial statements and related disclosures.

Concentrations of Credit Risk

For the three and nine months ended September 30, 2024, the Company did not report any revenues. For the three and nine months ended September 30, 2023, the Company derived 100% of its total revenue from a single source, the United States Government, in the form of federal research grants.

Revenue Recognition

The Company generates revenue from research and development grants under contracts with third parties that do not create customer-vendor relationships. The Company's research and development grants are non-exchange transactions and are not within the scope of ASC Topic 606, *Revenue from Contracts with Customers* ("ASC 606"). Contribution revenue earned from activities performed pursuant to research and development grants is reported as grant revenue in the Company's unaudited condensed consolidated statements of operations and comprehensive loss. Revenue from these grants is recognized as the Company incurs

qualifying expenses as stipulated by the terms of the respective grant. Cash received from grants in advance of incurring qualifying expenses is recorded as deferred revenue. The Company records revenue and a corresponding receivable when qualifying costs are incurred before the grants are received.

Research and Development Costs

Costs incurred in the research and development of the Company's product candidates are expensed as incurred. Research and development expenses consist of costs incurred in performing research and development activities, including activities associated with performing services under grant revenue contracts and include salaries and benefits, stock compensation, research-related subcontractors and consultants, supplies and overhead costs. Advance payments made to suppliers and contract research organizations are classified as prepaid research and development and are expensed as research and development as the supplies are consumed and the contract services are provided. During the three and nine months ended September 30, 2024, the Company incurred expenses of approximately $149 thousand and $446 thousand, respectively, with a related party vendor which were included in research and development expenses. During the three and nine months ended September 30, 2023, the Company incurred expenses of approximately $19 thousand and $30 thousand, respectively, with a related party vendor, which were included in research and development expenses. As of the periods ended September 30, 2024 and December 31, 2023, the Company had a payable or accrued expense balance with a related party vendor of approximately $74 thousand and $57 thousand, respectively, included in accounts payable and accrued expenses.

Leases

The Company accounts for its leases under ASU 2021-09, ASU 2018-10, and ASC Topic 842, *Leases* ("ASC 842"). ASC 842 requires a lessee to record a right-of-use asset and a corresponding lease liability for most lease arrangements on the Company's condensed and consolidated balance sheet. Under the standard, disclosure of key information about leasing arrangements to assist users of the condensed and consolidated financial statements with assessing the amount, timing and uncertainty of cash flows arising from leases is required.

Leases are classified as either finance leases or operating leases. A lease is classified as a finance lease if any one of the following criteria are met: the lease transfers ownership of the asset by the end of the lease term, the lease contains an option to purchase the asset that is reasonably certain to be exercised, the lease term is for a major part of the remaining useful life of the asset or the present value of the lease payments equals or exceeds substantially all of the fair value of the asset. A lease is classified as an operating lease if it does not meet any of these criteria.

For all leases at the lease commencement date, a right-of-use asset and a lease liability are recognized. The right-of-use asset represents the right to use the leased asset for the lease term. The lease liability represents the present value of the lease payments under the lease.

The right-of-use asset is initially measured at cost, which primarily comprises the initial amount of the lease liability, plus any initial direct costs incurred if any, less any lease incentives received. All right-of-use assets are reviewed for impairment. The lease liability is initially measured at the present value of the lease payments, discounted using the interest rate implicit in the lease or, if that rate cannot be readily determined, the secured incremental borrowing rate for the same term as the underlying lease.

Lease payments included in the measurement of the lease liability comprise the following: the fixed noncancelable lease payments, payments for optional renewal periods where it is reasonably certain the renewal period will be exercised, and payments for early termination options unless it is reasonably certain the lease will not be terminated early.

Lease cost for operating leases consists of the lease payments plus any initial direct costs, primarily brokerage commissions, and is recognized on a straight-line basis over the lease term. Included in lease cost are any variable lease payments incurred in the period that are not included in the initial lease liability and lease payments incurred in the period for any leases with an initial term of 12 months or less. Lease cost for finance leases consists of the amortization of the right-of-use asset on a straight-line basis over the lease term and interest expense determined on an amortized cost basis. The lease payments are allocated between a reduction of the lease liability and interest expense.

The Company has made an accounting policy election to not recognize leases with an initial term of 12 months or less within our condensed consolidated balance sheets and to recognize those lease payments on a straight-line basis in our condensed consolidated statements of operations and comprehensive loss over the lease term.

Equipment and Improvements

Equipment and improvements are stated at cost, less accumulated depreciation. For financial reporting purposes, depreciation is recognized using the straight-line method, allocating the cost of the assets over their estimated usefulness from three to five years for network equipment, office equipment, and furniture classified as fixed assets.

	Estimated Useful Economic Life
Leasehold property improvements, right-of-use assets	Lesser of lease term or useful life
Furniture and office equipment	3-5 years
Lab equipment	3 years
IT equipment	3 years

Fair Value Measurement

The Company has certain financial assets and liabilities recorded at fair value which have been classified as Level 1, 2 or 3 within the fair value hierarchy as described in the accounting standards for fair value measurements.

· Level 1 — Fair values are determined utilizing quoted prices (unadjusted) in active markets for identical assets or liabilities that the Company has the ability to access;
· Level 2 — Fair values are determined by utilizing quoted prices for identical or similar assets and liabilities in active markets or other market observable inputs such as interest rates, yield curves and foreign currency spot rates; and
· Level 3 — Inputs are unobservable inputs that reflect the Company's own assumptions about the assumptions market participants would use in pricing the asset or liability. Financial assets and liabilities are classified in their entirety based on the lowest level of input that is significant to the fair value measurement.

The Company's financial assets and financial liabilities, which include cash equivalents and marketable securities and accounts payable, have been initially valued at the transaction price, and subsequently revalued at the end of each reporting period, utilizing third-party pricing services. The pricing services utilize industry standard valuation models, including both income and market-based approaches, to determine value.

Marketable Securities

The Company's marketable securities consist of U.S. Treasury securities with maturities of less than one year which are classified as available-for-sale and included in current assets on the condensed consolidated balance sheets. Available-for-sale debt securities are carried at fair value with unrealized gains and losses reported as a component of stockholders' (deficit) equity in accumulated other comprehensive income. Realized gains and losses, if any, are included in other income, net in the condensed consolidated statements of operations and comprehensive loss.

Available-for-sale securities are reviewed for possible impairment at least quarterly, or more frequently if circumstances arise that may indicate impairment. When the fair value of the securities declines below the amortized cost basis, impairment is indicated and it must be determined whether it is other than temporary. Impairment is considered to be other than temporary if the Company: (i) intends to sell the security, (ii) will more likely than not be forced to sell the security before recovering its cost, or (iii) does not expect to recover the security's amortized cost basis. If the decline in fair value is considered other than temporary, the cost basis of the security is adjusted to its fair market value and the realized loss is reported.

4.Fair Value of Financial Instruments

The following table summarizes cash equivalents and marketable securities measured at their fair value on a recurring basis as of September 30, 2024 and December 31, 2023:

	Fair Value Measurements as of September 30, 2024:			
	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	$ 86,054	$ —	$ —	$ 86,054
Total	$ 86,054	$ —	$ —	$ 86,054
Marketable securities, available-for-sale:				
U.S. Treasury obligations	$ 2,330,226	$ —	$ —	$ 2,330,226
Total	$ 2,330,226	$ —	$ —	$ 2,330,226

	Fair Value Measurements as of December 31, 2023:			
	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	$ 8,039,024	$ —	$ —	$ 8,039,024
Total	$ 8,039,024	$ —	$ —	$ 8,039,024
Marketable securities, available-for-sale:				
U.S. Treasury obligations	$ 4,086,873	$ —	$ —	$ 4,086,873
Total	$ 4,086,873	$ —	$ —	$ 4,086,873

5.Marketable Securities

Marketable securities consisted of the following as of:

September 30, 2024	Amortized Cost	Unrealized Gain	Unrealized Loss	Fair Value
Marketable securities, available-for-sale:				
U.S. Treasury obligations	$ 2,328,472	$ 1,754	$ —	$ 2,330,226
Total	$ 2,328,472	$ 1,754	$ —	$ 2,330,226

December 31, 2023	Amortized Cost	Unrealized Gain	Unrealized Loss	Fair Value
Marketable securities, available-for-sale:				
U.S. Treasury obligations	$ 4,085,996	$ 877	$ —	$ 4,086,873
Total	$ 4,085,996	$ 877	$ —	$ 4,086,873

As of September 30, 2024, the Company held 11 U.S. Treasury debt securities that were in an unrealized gain position totaling $1,754. As of December 31, 2023, the Company held three U.S. Treasury debt securities that were in an unrealized gain position totaling $877. All U.S. Treasury obligations were due to mature in less than one year for the period and year ended September 30, 2024 and December 31, 2023, respectively.

The Company received proceeds of $12.1 million from maturities of marketable securities for the nine months ended September 30, 2024. The Company received proceeds of $41.1 million from maturities of marketable securities for the year ended December 31, 2023. The Company did not realize any gains or losses from maturities of marketable securities for the period ended September 30, 2024 or the year ended December 31, 2023.

6.Equipment and Improvements

Equipment and Improvements, net

	September 30, 2024	December 31, 2023
Furniture and office equipment	$ 86,930	$ 86,930
IT equipment	16,895	16,895
	103,825	103,825
Less: Accumulated depreciation	50,158	30,453
Total	$ 53,667	$ 73,372

Depreciation expense for the three and nine months ended September 30, 2024 was $6,568 and $19,705, respectively. Depreciation expense for the three and nine months ended September 30, 2023 was $6,568 and $170,830, respectively.

7.Supplemental Condensed Consolidated Balance Sheet Information

Accrued expenses and other current liabilities consist of the following:

	September 30, 2024	December 31, 2023
Accrued consulting	$ 78,447	$ 49,395
Accrued compensation	653,230	635,451
Accrued research and development	1,416,647	1,472,292
Accrued other	13,050	102,817
Total accrued expenses and other current liabilities	$ 2,161,374	$ 2,259,955

8. ATM Program

On February 1, 2024, the Company entered into an At The Market Offering (the “ATM”) with H.C. Wainwright & Co., LLC as sales agent (the “Agent”), pursuant to which the Company may, from time to time, issue and sell shares of its common stock, at an aggregate offering price of up to approximately $5.7 million (the “Shares”) through the Agent. Under the terms of the ATM Agreement with the Agent (the "ATM Agreement"), the Agent may sell the Shares at market prices by any method that is deemed to be an “ATM” as defined in Rule 415 under the Securities Act, as amended. On May 20, 2024, the Company reduced the aggregate offering price to $50,000, not including the shares of common stock previously sold.

9. Stockholders’ Equity (Deficit)

Each share of common stock is entitled to one vote. The holders of common stock are also entitled to receive dividends whenever funds are legally available and when declared by the board of directors, subject to the prior rights of holders of all classes of stock outstanding. As of September 30, 2024, a total of 3,337,435 shares of common stock were reserved for issuance upon the exercise of outstanding stock options and warrants under the 2020 Equity Incentive Plan (the "2020 Plan").

Share Issuances

Subject to the terms and conditions of the ATM Agreement, the Agent will use its commercially reasonable efforts to sell the Shares from time to time, based upon the Company’s instructions. The Company has no obligation to sell any of the Shares and may at any time suspend sales under the ATM Agreement or terminate the ATM Agreement in accordance with its terms. The Company has provided the Agent with customary indemnification rights, and the Agent will be entitled to a fixed commission of 3.0% of the aggregate gross proceeds from the Shares sold. The ATM Agreement contains customary representations and warranties, and the Company is required to deliver customary closing documents and certificates in connection with sales of the Shares. As of September 30, 2024, 315,338 ATM Shares have been sold under the ATM Agreement with net proceeds of $820,509 to the Company.

On May 20, 2024, the Company entered into a securities purchase agreement with a single institutional investor in connection with a registered direct offering and concurrent private placement with the same institutional investor (collectively the "May 2024 Offering"). The May 2024 Offering consisted of (i) 714,527 shares of the Company's common stock sold at $1.68 per share, (ii) Pre-Funded Common Warrants to purchase up to 957,925 shares of common stock with an exercise price of $0.0001 which are immediately exercisable after the issuance until exercised in full, (iii) Series A Common Warrants to purchase 1,672,452 shares of common stock with an exercise price of $1.68 per share which expire on the one-year anniversary from the date of stockholder approval, and (iv) Series B Common Warrants to purchase 1,672,452 shares of common stock with an exercise price of $1.68 per share which expire on the five-year anniversary from the date of stockholder approval. All of the warrants in the May 2024 Offering were issued to a single investor. During the third quarter 2024, the investor exercised 247,925 Pre-Funded Common Warrants and exercised the remaining 710,000 Pre-Funded Common Warrants as of the date of this report. The Company received net proceeds from the May 2024 Offering of approximately $2.2 million.

On May 20, 2024, the Company also entered into a warrant inducement agreement with the same investor to exercise certain outstanding warrants that the Company issued in January 2023 ("January 2023 Existing Warrants"). Pursuant to the warrant inducement agreement, the investor agreed to exercise outstanding warrants to purchase an aggregate of 708,500 shares of the Company's common stock at an amended exercise price of $1.68 per share. These shares are held in abeyance and not considered outstanding. The shares held in abeyance will be held in abeyance until notice from the investor that the balance, or portion thereof, may be issued in compliance with a beneficial ownership limitation provision in the warrants. The Company also agreed to reduce the exercise price of the remaining unexercised portion of such warrants to purchase 1,229,484 shares of common stock to $1.68 per share and to issue the investor Series C Common Warrants to purchase 708,500 shares of the Company's common stock and Series D Common Warrants to purchase 708,500 shares of the Company's common stock ("January 2023 New Warrants"). Each will have an exercise price of $1.68 per share and will be exercisable beginning on the effective date of stockholder approval. The Series C Common Warrants will expire on the one-year anniversary from the date of stockholder approval and the Series D Common Warrants will expire on the five-year anniversary from the date of stockholder approval. The shares held in abeyance were issued to the investor on October 9, 2024.

The repricing of the January 2023 Existing Warrants and issuance of the Series C Common Warrants and the Series D Common Warrants is considered a modification of the January 2023 Existing Warrants under the guidance of ASU 2021-04. The modification is consistent with the "Equity Issuance" classification under that guidance as the reason for the modification was to induce the holder to cash exercise their warrants, resulting in the imminent exercise of the January 2023 Existing Warrants, which raised equity capital and generated net proceeds for the Company of approximately $1.0 million. The total fair value of the consideration of the modification includes the incremental fair value of the January 2023 Existing Warrants (determined by comparing the fair values immediately prior to and immediately after the modification) and the initial fair value of the January 2023 New Warrants. The fair values were calculated using the Black-Scholes model and the Company determined that the total fair value of the consideration related to the modification of the January 2023 Existing Warrants, including the initial fair value of the January 2023 New Warrants was $1.8 million.

10. Stock-Based Compensation

2020 Equity Incentive Plan

The Company’s 2020 Plan was established for granting stock incentive awards to directors, officers, employees and consultants to the Company.

Stock Options

During the nine months ended September 30, 2024, the Company granted 308,039 options with a weighted average strike price of $1.89 to purchase common stock to certain employees that either (i) vest annually in three equal parts over three years (ii) vest on the first anniversary of the grant of such option in the amount of one-third of such grant, and the remaining portion will vest in 24 equal monthly installments thereafter or (iii) vest on the first anniversary of the grant of such option. The Company granted 45,000 performance-based options with a weighted average strike price of $2.16 to purchase common stock to certain employees. These options are subject to performance vesting and will vest and become exercisable once the performance conditions are probable of being met. There is no assurance that the performance conditions will be met and therefore some or all of these options may never vest or become exercisable. The total aggregate grant date fair value of all options granted was $489,108. During the nine months ended September 30, 2024, certain performance conditions were met.

During the nine months ended September 30, 2023, the Company granted 86,669 options with a weighted average strike price of $2.81 to purchase common stock to certain employees that will either (i) vest annually in three equal parts over three years or (ii) vest

on the first anniversary of the grant of such option in the amount of one-third of such grant, and the remaining portion will vest in 24 equal monthly installments thereafter. The Company granted 25,000 performance-based options with a weighted average strike price of $1.33 to purchase common stock to certain employees. These options are subject to performance vesting and will vest and become exercisable once the performance conditions have been met. There is no assurance that the performance conditions will be met and therefore some or all of these options may never vest or become exercisable. The total aggregate grant date fair value of all options granted was $338,741. During the nine months ended September 30, 2023, no performance conditions were met.

For awards with performance conditions in which the award does not vest unless the performance condition is met, we recognize expense if, and to the extent that, we estimate that achievement of the performance condition is probable. If we conclude that vesting is probable, we recognize expense from the date we reach this conclusion through the estimated vesting date.

Stock-Based Compensation Expense

The following table summarizes the stock-based compensation expense for stock options granted to employees and non-employees:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Research and development	$ 84,370	$ 41,842	$ 94,594	$ 120,718
Selling, general and administrative	63,654	87,939	137,561	257,181
Total stock-based compensation expense	$ 148,024	$ 129,781	$ 232,155	$ 377,899

11.Net Loss Per Share

The following table presents the calculation of basic and diluted net loss per share applicable to common stockholders. Basic net loss per share is calculated by dividing net loss attributable to common shareholders by the weighted-average number of shares outstanding during the period which includes Pre-Funded Warrants and shares held in abeyance from date of issuance.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Numerator:				
Net loss	$ (5,778,066)	$ (4,595,199)	$ (15,387,309)	$ (14,850,943)
Denominator:				
Weighted-average number of common shares outstanding – basic and diluted	8,882,570	6,162,671	7,592,103	5,977,841
Net loss per share applicable to common stockholders – basic and diluted	$ (0.65)	$ (0.75)	$ (2.03)	$ (2.48)

The following shares were excluded from the calculation of diluted net loss per share applicable to common stockholders, prior to the application of the treasury stock method, because their effect would have been anti-dilutive for the periods presented:

	Nine Months Ended September 30,	
	2024	2023
Options to purchase shares of stock	1,140,280	835,913
Warrants to purchase shares of stock	7,738,040	3,080,090
Total	8,878,320	3,916,003

12.Income Taxes

During the three and nine months ended September 30, 2024 and 2023, there was no provision for income taxes as the Company incurred losses during those periods. Deferred tax assets and liabilities reflect the net tax effect of temporary differences between the carrying amount of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. The Company

recorded a full valuation allowance against its deferred tax assets as the Company believes it is more likely than not the deferred tax assets will not be realized.

13.Commitments and Contingencies

Litigation

As previously disclosed, on April 26, 2024, the Company received a notice of a demand for arbitration with the American Arbitration Association from Pivot Holding LLC ("Pivot"), a successor in interest to Sphaera Pharma Pte. Ltd. ("Sphaera"), in connection with the Collaborative Research and Development Agreement dated February 29, 2012, as amended, between the Company and Sphaera (the "Collaboration Agreement"), alleging breach of contract by the Company for failure to pay certain milestone payments under the Collaboration Agreement and seeking damages. Also as previously disclosed, on June 17, 2024, the Company filed an answering statement and counterclaim denying that it had breached the Collaboration Agreement and counterclaiming. On September 30, 2024, following a non-binding confidential mediation, the Company and Pivot entered into a settlement agreement (the "Settlement Agreement") pursuant to which the Company agreed to pay to Pivot a total sum of $500,000, which Pivot agreed shall constitute full and complete payment for, and shall fully satisfy, any and all amounts for any and all project milestone payments owed or that may be owed to Sphaera and/or Pivot by the Company under the Collaboration Agreement for: (i) "First dosing of patient in US phase 1 trial"; (ii) "US Phase 1 trial completion with endpoints met"; and (iii) "US Phase 2 trial completion with endpoints met" (each as described in the Collaboration Agreement) which payments would have totaled $1.625 million in the event Pivot were to be successful in claiming that the Company conducted Phase 1 and Phase 2 trials or that would be due upon successful milestones in the future. The Company also agreed to pay to Pivot a one-time payment of $4.4 million, increased from $4.0 million, upon FDA Approval (as described in the Collaboration Agreement) and the parties agreed that no further FDA Approval milestone payment(s) shall be due to Pivot in the event that the Company receives additional FDA Approval(s). The Settlement Agreement contains customary mutual releases and covenants not to sue. Except as otherwise provided in the Settlement Agreement, all terms in the Collaboration Agreement shall remain in full force and effect.

Lease

On April 18, 2022, the Company entered into an operating lease agreement for office space at its new location in Lexington, Massachusetts (the "Office Lease"). On August 8, 2022, the Company commenced occupancy of the leased space. The lease runs through September 30, 2025. We have an option to extend the lease term for an additional three (3) years thereafter.

The Company accounts for the Office Lease under the provisions of ASC 842. We recorded a right-of-use asset and a corresponding operating lease liability on the Company's condensed consolidated balance sheets upon the accounting commencement date in August 2022. The lease liability was measured at the accounting commencement date utilizing a 12% discount rate. The right-of-use asset had a balance of $133,105 at September 30, 2024. The operating lease obligations totaled $145,210 at September 30, 2024, all of which is included under current liabilities. The Company recorded lease expense of $35,296 and $105,887 and other short-term payments of $5,521 and $16,827 for the three and nine months ended September 30, 2024, respectively, in selling, general and administrative expenses and lease expense relating to the Office Lease of $35,296 and $105,887 and other short-term payments of $5,788 and $17,364 for the three and nine months ended September 30, 2023, respectively, in selling, general and administrative expenses.

The Office Lease contains escalating payments during the lease period. Upon execution of the Office Lease, the Company prepaid one month of rent and a security deposit, one of which will be held in escrow and credited at the termination of the lease and the other of which will be applied to the first month's rent.

As of September 30, 2024, a security deposit of approximately $25,000 was included in prepaid expenses and other current assets on the Company's condensed consolidated balance sheet related to the Office Lease.

Future minimum lease payments under this lease at September 30, 2024, are presented by calendar year as follows:

Year		
2024	$	38,322
2025		114,966
Total lease payments		153,288
Less: imputed interest		(8,078)
Present value of operating lease liabilities	$	145,210

14. Subsequent Event

On October 21, 2024, the Company announced the closing of a private placement of approximately $110 million from the issuance and sale of shares of the Company's common stock and accompanying warrants with potential aggregate financing of up to approximately $275 million upon the full cash exercise of the warrants issued in the private placement, before deducting placement agent fees and offering expenses (the "October 2024 Offering"). The October 2024 Offering consisted of (i) 58,310,000 shares of common stock sold at $1.37 per share, or, in lieu thereof, pre-funded warrants ("Pre-Funded Warrants") to purchase up to 21,985,000 shares of common stock with an exercise price of $0.001, (ii) Series A-1 Warrants to purchase an aggregate of 40,139,474 shares of common stock with an exercise price of $1.37, or in lieu thereof, Pre-Funded Warrants to purchase the same number of shares of common stock (the "Series A-1 Warrants"), and (iii) Series B-1 Warrants to purchase an aggregate of 73,813,529 shares of common stock with an exercise price of $1.37, or in lieu thereof, Pre-Funded Warrants to purchase the same number of shares of common stock (the "Series B-1 Warrants"). The Pre-Funded Warrants and Pre-Funded Warrants underlying the Series A-1 Warrants and Series B-1 Warrants are exercisable at any time after their original issuance and will not expire. The Series A-1 Warrants and the Series B-1 Warrants will become exercisable at the earlier of (a) the 75th calendar day following the initial filing of the resale registration statement covering the resale of the shares of common stock issuable upon the exercise of the Series A-1 Warrants and Series B-1 Warrants, if the SEC notifies the Company that it will review such resale registration statement and (b) the 5th business day after the date the Company is notified by the SEC that such resale registration statement will not be subject to further review. Each Series A-1 Warrant will be exercisable for one share of common stock and will expire at 5:00 p.m. (New York City time) on the 30th day following the later of (a) the Company's public announcement of the Phase 2b 12 week safety readout for IkT-001Pro for PAH and (b) the Company both obtaining stockholder approval for and filing an amendment to its charter to increase the number of authorized shares of common stock to a number of shares of common stock sufficient to allow for the full exercise of the warrants (the "Charter Amendment"). Each Series B-1 Warrant will be exercisable for one share of common stock, will become exercisable by an investor once all of such investor's Series A-1 Warrants have been exercised and will expire at 5:00 p.m. (New York City time) on the 30th day following the later of (a) the Company's public announcement of its Phase 2b efficacy readout for IkT-001Pro with respect to PAH and (b) the Company both obtaining stockholder approval for and filing the Charter Amendment. The Series A-1 Warrants have an exercise price of $1.37 per share and the Series B-1 Warrants have an exercise price of $1.49 per share. The Company intends to use the net proceeds from the private placement to finance the initiation of a Phase 2b trial in PAH and for general corporate purposes.

As a result of the October 2024 Offering, as of November 1, 2024, we had 67,192,570 shares of common stock outstanding and 21,985,000 pre-funded warrants outstanding.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

Forward-Looking Statements

This Quarterly Report on Form 10-Q ("Report") (including but not limited to this Item 2, "Management's Discussion and Analysis of Financial Condition and Results of Operations") contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), that are intended to qualify for the "safe harbor" created by those sections. In addition, we may make forward-looking statements in other documents filed with or furnished to the SEC, and our management and other representatives may make forward-looking statements orally or in writing to analysts, investors, representatives of the media and others. You should read the following discussion and analysis of our financial condition and results of operations together with our unaudited condensed consolidated financial statements and the related notes to those statements included elsewhere in this Report. This discussion and analysis and other parts of this Report contain forward-looking statements based upon current beliefs, plans and expectations related to future events and our future financial performance that involve risks, uncertainties and assumptions, such as statements regarding our intentions, plans, objectives, expectations, forecasts and projections. Our actual results and the timing of selected events could differ materially from those anticipated in these forward-looking statements as a result of several factors.

All statements included or incorporated by reference in this Report, other than statements or characterizations of historical fact, are forward-looking statements. Forward-looking statements can generally be identified by the fact that they do not relate strictly to historical or current facts and include, but are not limited to, statements using terminology such as "can", "may", "could", "should", "assume", "forecasts", "believe", "designed to", "will", "expect", "plan", "anticipate", "estimate", "potential", "position", "predicts", "strategy", "guidance", "intend", "seek", "budget", "project" or "continue", or the negative thereof or other comparable terminology regarding beliefs, plans, expectations or intentions regarding the future. You should read statements that contain these words carefully because they:

- discuss our future expectations;
- contain projections of our clinical trials, future results of operations or of our financial condition; and
- state other "forward-looking" information.

We believe it is important to communicate our expectations. However, forward-looking statements are based on our current expectations, assumptions, estimates, approximations and projections about our business and our industry and management's beliefs, all of which are subject to change. Forward-looking statements are not guarantees of future performance and are subject to known and unknown risks, uncertainties and other factors. Accordingly, our actual results and the timing of certain events may differ materially and adversely from those expressed or implied in such forward-looking statements due to a variety of factors and risks, including, but not limited to, those set forth in this Item 2, "Management's Discussion and Analysis of Financial Condition and Results of Operations" and in our unaudited condensed consolidated financial statements and notes thereto included in this Report, those set forth from time to time in our other filings with the SEC, including our Annual Report on Form 10-K for the fiscal year ended December 31, 2023, and the following factors and risks:

- We are a clinical-stage drug development company with limited resources, a limited operating history and have no products approved for commercial sale, which may make it difficult to evaluate our current business and predict our future success and viability;
- If we are unable to successfully raise additional capital, particularly with respect to our neurodegenerative programs, our future clinical trials and product development could be limited and our long-term viability may be threatened;
- While the U.S. Food and Drug Administration, or FDA, lifted the clinical holds with respect to the risvodetinib (IkT-148009) programs relating to Parkinson's disease and Multiple System Atrophy, or MSA, we may be subject to further clinical holds by the FDA in the future;
- IkT-001Pro may not improve the side effect profile compared to imatinib mesylate or may not be effective as an add-on treatment for PAH;
- Drug development is a highly uncertain undertaking and involves a substantial degree of risk. We have never generated any revenue from product sales, we may never generate any revenue from product sales, and we may fail to generate further revenue from grants or contracts or to be profitable;
- The wars between Russia and Ukraine and between Israel and Hamas could materially adversely affect our business, results of operations, and financial condition;

•Our results of operations have been adversely affected and, in the future, could be materially adversely impacted by the COVID-19 virus;

•Adverse developments affecting financial institutions, companies in the financial services industry or the financial services industry generally, including those we do business with, could adversely affect our operations and liquidity;

•We have incurred significant net losses since our inception and anticipate that we will continue to incur net losses for the foreseeable future;

•Due to the significant resources required for the development of our programs, and depending on our ability to access capital, we must prioritize development of certain product candidates;

•We currently contract with various research institutions to perform the research and development activities needed to develop our products, and if we ever choose to or need to find alternative research institutions, we may not be able to do so at all or, if we are able to do so, it may be costly and may cause significant delays in the development and commercialization of our products;

•Positive results from early preclinical or clinical studies of our product candidates are not necessarily predictive of the results of later preclinical studies and any current and future clinical trials of our product candidates;

•We have no history of completing clinical trials for novel drug substances or commercializing pharmaceutical products, which may make it difficult to evaluate the prospects for our future viability;

•Our clinical trials may reveal significant adverse events, toxicities or other side effects not seen in our preclinical studies and may result in a safety profile that could inhibit regulatory approval or market acceptance of any of our product candidates;

•We have concentrated much of our research and development efforts to date on the treatment of neurodegenerative diseases, a field that has seen limited success in drug development, although we now intend to expend considerable resources on PAH;

•We may encounter substantial delays in our current and planned clinical trials, or may not be able to conduct or complete our clinical trials on the timelines we expect, if at all;

•Our current and planned clinical trials may fail to demonstrate substantial evidence of the safety and efficacy of our product candidates, which would prevent, delay or limit the scope of regulatory approval and commercialization;

•Clinical development is a lengthy and expensive process with an uncertain outcome, and failure can occur at any stage of clinical development;

•The manufacture of our product candidates is complex and difficulties may be encountered in production;

•If, in the future, we are unable to establish sales and marketing capabilities or enter into agreements with third parties to sell and market any product candidates we may develop, we may not be successful in commercializing those product candidates if and when they are approved;

•Even if any product candidates we develop receive marketing approval, they may fail to achieve the degree of market acceptance by physicians, patients, healthcare payors, and others in the medical community necessary for commercial success;

•Even if we are able to commercialize any product candidates, such products may become subject to unfavorable pricing regulations, third-party reimbursement practices, or healthcare reform initiatives, which would harm our business;

•The regulatory approval processes of the FDA, European Medicines Agency, and comparable foreign regulatory authorities are lengthy, time consuming, and inherently unpredictable. Regulatory authorities have substantial discretion in the approval process and may refuse to accept an application, may disagree with our regulatory strategy or proposed pathway for approval or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies;

•We expect to depend in whole or in part on collaborations with third parties for the research, development and commercialization of any product candidates we may develop;

•We contract with third parties for the manufacture of materials for our research programs, preclinical studies and current clinical trials and expect to continue to do so for any future clinical trials and for commercialization of any product candidates that we may develop;

•We depend on a small number of third-party suppliers for key raw materials used in the manufacturing processes for our product candidates, and the loss of these third-party suppliers or their inability to supply us with adequate raw materials could harm our business; and

•If we are unable to obtain and maintain patent protection for any product candidates we develop, our competitors could develop and commercialize products or technology similar or identical to ours, and our ability to successfully commercialize any product candidates we may develop, and our technology may be adversely affected.

Any or all of our forward-looking statements may turn out to be wrong. They may be affected by inaccurate assumptions that we might make or by known or unknown risks and uncertainties. Actual outcomes and results may differ materially from what is expressed or implied in our forward-looking statements.

All forward-looking statements included in this Report are made as of the date hereof, in each case based on information available to us as of the date hereof, and we assume no obligations to update any forward-looking statement or risk factor, unless we are required to do so by law. If we do update one or more forward-looking statements, no inference should be drawn that we will make updates with respect to other forward-looking statements or that we will make any further updates to those forward-looking statements at any future time.

Forward-looking statements may include our plans and objectives for future operations, including plans and objectives relating to our product candidates and our future economic performance, projections, business strategy and timing and likelihood of success. Assumptions relating to the forward-looking statements included in this Report involve judgments with respect to, among other things, future economic, competitive and market conditions, future business decisions, and the time and money required to successfully complete development and commercialization of our product candidates, all of which are difficult or impossible to predict accurately and many of which are beyond our control.

Any of the assumptions underlying the forward-looking statements contained in this Report could prove inaccurate and, therefore, we cannot assure you that any of the results or events contemplated in any of such forward-looking statements will be realized. Based on the significant uncertainties inherent in these forward-looking statements, the inclusion of any such statement should not be regarded as a representation or as a guarantee by us that our objectives or plans will be achieved, and we caution you against relying on any of the forward-looking statements contained herein.

Overview

We are a clinical-stage pharmaceutical company developing protein kinase inhibitor therapeutics to modify the course of cardiopulmonary and neurodegenerative diseases and other diseases that arise from aberrant signaling through the Abelson Tyrosine Kinases. The Company's multi-therapeutic pipeline has developed IkT-001Pro, a prodrug of the anticancer agent imatinib mesylate, for Pulmonary Arterial Hypertension (PAH). In 2023, the Company completed a bioequivalence clinical trial in healthy volunteers to determine the dose of IkT-001Pro that is equivalent to either 400 mg or 600 mg imatinib mesylate and the results are being utilized to set the doses in a Phase 2b trial to determine if IkT-001Pro could be a disease-modifying treatment for PAH. The Company has also developed risvodetinib (also known as IkT-148009), a selective inhibitor of the non-receptor Abelson Tyrosine Kinases that targets the treatment of Parkinson's disease inside and outside the brain. In 2021, the Company commenced clinical development of risvodetinib. In 2023, the Company initiated the Phase 2 201 trial for risvodetinib (IkT-148009) as a treatment for Parkinson's disease and completed that trial on October 6, 2024. We expect results from this trial to be reported in the fourth quarter of 2024.

IkT-001 Pro and PAH. IkT-001Pro emerged from the Company's medicinal chemistry program that aimed to improve on-dosing side effects for drugs that inhibit the Abelson Tyrosine Kinase family. IkT-001Pro, a prodrug of the anticancer agent imatinib mesylate, was designed to mask areas of the molecule that might play a role in the on-dosing GI and other side effects commonly observed with oral imatinib mesylate. A three-part dose finding/dose equivalence study in 66 healthy volunteers (known as 'the 501 trial') was completed with IkT-001Pro in 2023. The study was designed to evaluate the 96-hour single-dose pharmacokinetics of imatinib delivered as IkT-001Pro and determine the dose of IkT-001Pro that can deliver the equivalent of either 400 mg or 600 mg imatinib mesylate. Bioequivalence to 400 mg imatinib mesylate was established to our satisfaction for a 600 mg dose of IkT-001Pro. We further evaluated 600 mg imatinib mesylate and believe that a dose between 800 mg and 900 mg of IkT-001Pro is the preferred dose of IkT-001Pro to deliver a dose of imatinib equivalent to 600 mg imatinib mesylate. On January 19, 2024, members of the Company along with its medical consultants met with the FDA Hematological Malignancy Review Team (the "Review Team") in a Pre-New Drug Application, or pre-NDA, meeting to discuss our bioequivalence studies of IkT-001Pro and its path to approval. All questions were addressed and summarized in official meeting minutes issued by the FDA on February 12, 2024. During the meeting, we inquired whether additional clinical studies would be needed to seek approval and discussed manufacturing and quality control requirements for approval. The Review Team acknowledged that the 505(b)(2) pathway appeared to be the appropriate pathway for approval of IkT-001Pro and indicated that, pending formal review of our clinical data, clinical studies completed to date indicate that

600 mg and 800 mg IkT-001Pro provide similar exposures to 400 mg and 600 mg imatinib mesylate, respectively. The Review Team also discussed the possible difference between IkT-001Pro and imatinib mesylate absorption in the gut and recommended that we evaluate whether IkT-001Pro and imatinib mesylate behave differently with respect to certain gut transporters that regulate absorption. This evaluation was completed and determined that IkT-001Pro and imatinib mesylate have similar behavior toward the transporters P-glycoprotein (PGP) and the Breast Cancer Resistance Protein BCRP. Finally, a number of recommendations were discussed to prevent the potential mix-up between IkT-001Pro and imatinib mesylate either at the pharmacy or by patients for two drugs delivering the same active ingredient. The Company discussed alternate dosage forms for IkT-001Pro relative to imatinib mesylate as the primary mitigation strategy and will provide a justification of the dosage forms chosen and why they are unlikely to cause medication errors if/when the Company submits an NDA for approval of IkT-001Pro in these cancer indications.

In 2013, the outcome of a Phase 3 trial evaluating imatinib mesylate as a treatment for PAH was reported, demonstrating that imatinib can modify the course of disease in PAH. Co-administration of medications with harmful drug-drug interactions precluded the approval of imatinib as add-on therapy in PAH despite the success of the Phase 3 trial. PAH is a rare disease of the pulmonary microvasculature, with about 30,000 cases in the U.S. that principally afflicts women between the ages of 30 and 60. The global PAH market size was valued at $7.66 billion in 2023 and is estimated to grow at a compound annual growth rate (CAGR) of 5.4% between 2024 to 2030. As the Company considered revisiting the use of imatinib in PAH, the Company recognized that changes in standard-of-care for these patients may have alleviated much of the safety risk previously observed for imatinib in PAH patients. This analysis prompted the Company to file a pre-IND (PIND) meeting request to discuss the application of IkT-001Pro as a potential disease-modifying treatment for PAH. To evaluate this further, members of the Company met with the FDA Division of Cardiology and Nephrology in a PIND meeting to discuss the Company's plan to utilize IkT-001Pro at 300 mg or 500 mg in a Phase 2b efficacy, safety and tolerability study in PAH. At the meeting, the FDA confirmed that IkT-001Pro would be viewed as a New Molecular Entity (NME) and that the appropriate path for approval remained to be the 505(b)(2) statute. This opens up the possibility of IkT-001Pro being granted NME status and patent exclusivity on approval. The FDA requested at the PIND meeting that we conduct a comparative cell-culture based study of the hERG ion channel, a standard cardiovascular safety test performed for any NME for which a new IND is to be opened. Neither IkT-001Pro nor imatinib mesylate were found to be inhibitors of hERG. Following completion of this study, the IND was filed with the FDA on August 9, 2024 and cleared to initiate a Phase 2b trial on September 9, 2024. On October 21, 2024, the Company closed a private placement with an initial investment of approximately $110 million, before deducting placement fees and offering expenses, to support this program. If the warrants are exercised for cash, the aggregate financing may be up to $275 million. The Company intends to use the net proceeds from the private placement to finance the initiation of a Phase 2b trial in PAH and for general corporate purposes. The Company has also applied for Orphan Drug Designation for delivery of imatinib by IkT-001Pro for PAH.

Risvodetinib and neurodegenerative diseases. Risvodetinib emerged from the Company's RAMP™ medical chemistry program and was shown to be a selective inhibitor of the non-receptor Abelson Tyrosine Kinases. In a series of pre-clinical studies, including therapeutic dosing animal models of inherited and sporadic Parkinson's disease, risvodetinib was shown to be an effective, disease-modifying therapeutic. These studies established that risvodetinib is capable of protecting neurons from degradation, restoring lost motor and non-motor function, suppressing neuroinflammation and clearing the pathology arising from alpha-synuclein aggregate deposition in animal models of human disease. These studies prompted clinical development of risvodetinib in patients in untreated Parkinson's disease. The Phase 2 '201 Trial' was a twelve-week study of three doses of risvodetinib in participants who have untreated Parkinson's disease and was placebo controlled with 1:1:1:1 randomization. The primary endpoints of this trial were safety and tolerability and a secondary endpoint included a hierarchy of 15 endpoints whose purpose was to evaluate treatment benefit in the brain and GI tract. The 201 Trial was completed on October 6, 2024 and trial outcomes are anticipated to be made public in the fourth quarter of 2024.

In March 2023, we opened our IND to evaluate risvodetinib (IkT-148009) as a treatment for the Parkinson's-related orphan disease Multiple System Atrophy, or MSA. Our evaluation of risvodetinib (IkT-148009) in MSA was benefited by a grant received from the National Institute of Neurological Diseases and Stroke, an Institute of the National Institutes of Health, for $0.39 million to fund animal model studies of risvodetinib (IkT-148009) as a therapy for MSA. Two different animal studies were undertaken to evaluate whether risvodetinib (IkT-148009) could have an impact on disease in the animal. One model evaluated the ability of risvodetinib (IkT-148009) to modify disease early in its progression, while the second model is evaluating whether risvodetinib (IkT-148009) can correct functional loss much later in the disease course. The early progression model study has now been shown to preserve nearly normal functional activity following 20 weeks of once daily dosing relative to untreated controls. Preservation of function in this model occurred with substantial reduction of the underlying alpha-synuclein protein pathology. The second model evaluating risvodetinib (IkT-148009) late in the disease course is ongoing. In addition, risvodetinib (IkT-148009) was recently given Orphan Drug Designation by the FDA for the treatment of MSA. We are working with the National Institute of Neurological Diseases and Stroke to possibly initiate a Phase 2/3 program to evaluate risvodetinib (IkT-148009) as a treatment for MSA through a clinical trial network supported by the Institute. The proposed Phase 2/3 study will have a primary efficacy endpoint following once daily dosing at one of two dose levels for twelve months. We plan to submit complementary regulatory documents for risvodetinib (IkT-148009) to European Union authorities in 2024 or 2025.

We have also improved drug delivery of risvodetinib (IkT-148009) through development of a tablet formulation, which we measured to nearly double the concentration of risvodetinib (IkT-148009) delivered relative to the same dose previously administered as a gelatin capsule. This provides the opportunity to lower the effective oral dose, which could lead to further safety and tolerability improvements for risvodetinib (IkT-148009). The Company plans to introduce the tablet formulation into the 12-month extension study, once implemented, as well as in all future clinical trials.

Finally, we are evaluating a number of research phase molecules (IkT-148x and BIP 4-7) for a variety of neurodegenerative disease indications across our pre-clinical development pipeline. A similar effort has begun to identify novel, second generation candidate molecules for PAH.

To increase the probability of success, we are making parallel investments in several product candidates and back-up candidates, and plan to advance only those candidates to the later stages of clinical development that show strong preclinical and early clinical data. By developing a portfolio of product candidates across therapeutic indications, we can continuously apply learnings and tools across programs and leverage economies of scale in our research and development organization. Our target indications include orphan indications, such as PAH and Multiple System Atrophy, and diseases with large patient populations, such as PD.

We currently have commercialization rights to all of our development programs and patent protection in the United States until 2033 for IkT-001Pro and 2036 for risvodetinib (IkT-148009). Additional patent filings could extend this period of exclusivity.

Components of Operating Results

Operating Expenses

Research and Development

Research and development activities account for a significant portion of our operating expenses. We record research and development expenses as incurred. Research and development expenses incurred by us for the discovery and development of our product candidates and prodrug technologies include:

- external research and development expenses, including expenses incurred under arrangements with third parties, such as CROs, preclinical testing organizations, clinical testing organizations, CMOs, academic and non-profit institutions and consultants;
- fees related to our license and collaboration agreements;
- personnel related expenses, including salaries, benefits and non-cash stock-based compensation expense; and
- other expenses, which include direct and allocated expenses for laboratory, facilities and other costs.

A portion of our research and development expenses are direct external expenses, which we track on a program-specific basis from inception of the program.

Program expenses include expenses associated with our most advanced product candidates and the discovery and development of compounds that are potential future candidates. We also track external expenses associated with our third-party research and development efforts. All external costs are tracked by therapeutic indication. We do not track personnel or other operating expenses incurred for our research and development programs on a program-specific basis. These expenses primarily relate to salaries and benefits and stock-based compensation and office consumables.

At this time, we can only estimate the nature, timing and costs of the efforts that will be necessary to complete the development of, and obtain regulatory approval for, any of our product candidates. We are also unable to predict when, if ever, material net cash inflows will commence from sales or licensing of our product candidates. This is due to the numerous risks and uncertainties associated with drug development, including the uncertainty of:

- our ability to add and retain key research and development personnel and other key employees;
- our ability to successfully file IND and NDA applications with the FDA;
- our ability to conduct and commence trials;
- our ability to establish an appropriate safety profile with IND-enabling toxicology studies;
- our ability to successfully develop, obtain regulatory approval for, and then successfully commercialize, our product candidates;

- our successful enrollment in and completion of our current and future clinical trials;
- the costs associated with the development of any additional product candidates we identify in-house or acquire through collaborations;
- our ability to discover, develop and utilize biomarkers to demonstrate target engagement, pathway engagement and the impact on disease progression of our molecules;
- our ability to establish agreements with third party manufacturers for clinical supply for any future clinical trials and commercial manufacturing, if our product candidates are approved;
- the terms and timing of any collaboration, license or other arrangement, including the terms and timing of any milestone payments thereunder;
- our ability to obtain and maintain patent, trade secret and other intellectual property protection and regulatory exclusivity for our product candidates if and when approved;
- our receipt of marketing approvals from applicable regulatory authorities;
- the impact of the outbreak of the COVID-19 pandemic or other future pandemics;
- our ability to commercialize products, if and when approved, whether alone or in collaboration with others; and
- the continued acceptable safety profiles of the product candidates following approval.

A change in any of these variables with respect to the development of any of our product candidates would significantly change the costs, timing and viability associated with the development of that product candidate. We expect our research and development expenses to increase for the next several years as we continue to implement our business strategy, advance our current programs, expand our research and development efforts, seek regulatory approvals for any product candidates that successfully complete clinical trials, access and develop additional product candidates and incur expenses associated with hiring additional personnel to support our research and development efforts. In addition, product candidates in later stages of clinical development generally incur higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials.

Our direct research and development expenses consist principally of external costs, such as fees paid to investigators, consultants, central laboratories and CROs in connection with our clinical studies, and costs related to acquiring and manufacturing clinical study materials. We allocate salary and benefit costs directly related to specific programs. We do not allocate personnel-related discretionary bonus or stock-based compensation costs, laboratory and related expenses, depreciation or other indirect costs that are deployed across multiple projects under development and, as such, the costs are separately classified as other research and development expenses in the table below:

	Three Months Ended September 30,		
	2024	2023	Change
PD	$ 2,776,009	$ 2,671,665	$ 104,344
MSA	43,968	76,224	(32,256)
CML	360,823	247,291	113,532
PAH	814,424	—	814,424
Other research and development expenses	194,649	230,371	(35,722)
Total research and development expenses	$ 4,189,873	$ 3,225,551	$ 964,322

	Nine Months Ended September 30,		
	2024	2023	Change
PD	$ 7,786,014	$ 6,922,450	$ 863,564
MSA	138,273	255,630	(117,357)
CML	485,446	2,559,294	(2,073,848)
PAH	815,474	—	815,474
Other research and development expenses	791,775	877,994	(86,219)
Total research and development expenses	$ 10,016,982	$ 10,615,368	$ (598,386)

Selling, General and Administrative

Selling, general and administrative expenses include personnel related expenses, such as salaries, benefits, travel and non-cash stock-based compensation expense, expenses for outside professional services and allocated expenses. Outside professional services consist of legal, accounting and audit services, investor relations services and other consulting fees. Allocated expenses consist of rent expenses related to our offices in Lexington, Massachusetts and Atlanta, Georgia not otherwise included in research and development expenses.

We are incurring additional expenses as compared to when we were a private company, including expenses related to compliance with the rules and regulations of the SEC and those of Nasdaq, additional insurance expenses, investor relations activities and other administrative and professional services. We also are increasing our administrative headcount as a public company and as we advance our product candidates through clinical development, which will also likely require us to increase our selling, general and administrative expenses.

Results of Operations

Comparison of the Three Months Ended September 30, 2024 and 2023

The following table sets forth the significant components of our results of operations:

	For the Three Months Ended September 30,		Change	
	2024	2023	($)	(%)
	(unaudited)			
Grant revenue	$ —	$ 79,569	$ (79,569)	(100.0)
Research and development	(4,189,873)	(3,225,551)	(964,322)	29.9
Selling, general and administrative	(1,637,603)	(1,622,894)	(14,709)	0.9
Loss from operations	(5,827,476)	(4,768,876)	(1,058,600)	(22.2)
Interest income	49,410	173,677	(124,267)	(71.6)
Net loss	$ (5,778,066)	$ (4,595,199)	$ (1,182,867)	(25.7)

Grant Revenue

Grant revenue for the three months ended September 30, 2024, decreased by $79,569 or 100.0% to $0 from $79,569 in the prior comparable period. During 2024, the Company continued to advance its Phase I and II clinical trials for PD which were not submitted for grant revenue. The Company has no active grants during the period ended September 30, 2024.

Research and Development

Research and development expenses increased by $964,322 or 29.9% to $4,189,873 from $3,225,551 in the prior comparable period. The $1.0 million increase in research and development expenses was due to an increase of $0.8 million in PAH expenses and a net increase of $0.2 million in other research and development expenses.

Selling, General and Administrative

Selling, general and administrative expenses increased by $14,709 or 0.9% to $1,637,603 from $1,622,894 in the prior comparable period. The $14,709 increase was primarily driven by a $273,000 decrease in advertising and promotion, an $80,000 decrease in D&O insurance and a $338,000 net increase in all other normal selling, general and administrative expenses.

Interest Income

Interest income decreased by $124,267 or 71.6% to $49,410 from $173,677 in the prior comparable period. The decrease was driven by a reduction in interest earned on U.S. Treasuries and money market instruments.

Comparison of the Nine Months Ended September 30, 2024 and 2023

The following table sets forth the significant components of our results of operations:

	For the Nine Months Ended September 30,		Change	
	2024	2023	($)	(%)
	(unaudited)			
Grant revenue	$ —	$ 260,500	$ (260,500)	(100.0)
Research and development	(10,016,982)	(10,615,368)	598,386	(5.6)
Selling, general and administrative	(5,643,386)	(5,331,358)	(312,028)	5.9
Loss from operations	(15,660,368)	(15,686,226)	25,858	(0.2)
Interest income	273,059	835,283	(562,224)	(67.3)
Net loss	$ (15,387,309)	$ (14,850,943)	$ (536,366)	3.6

Grant Revenue

Grant revenue for the nine months ended September 30, 2024, decreased by $260,500 or 100% to $0 from $260,500 in the prior comparable period. During 2024, the Company continued to advance its Phase I and Phase II clinical trials for PD which were not submitted for grant revenue. The Company has no active grants during the period ended September 30, 2024.

Research and Development

Research and development expenses decreased by $598,386 or 5.6% to $10,016,982 from $10,615,368 in the prior comparable period. The $0.6 million decrease in research and development expenses was due to a decrease of $2.1 million in CML expenses due to the completion of the three-part dose finding equivalence study in 2023 partially offset by an increase of $0.8 million in PAH expenses, a $0.9 million increase in risvodetinib (IkT-148009) expenses and a net decrease of $0.2 million in other research and development expenses.

Selling, General and Administrative

Selling, general and administrative expenses increased by $312,028 or 5.9% to $5,643,386 from $5,331,358 in the prior comparable period. The $0.3 million increase was primarily driven by a $0.7 million increase in legal and consulting fees partially offset by a $0.2 million decrease in D&O insurance, a $0.3 million decrease in advertising and promotions and a $0.1 million net increase in all other normal selling, general and administrative expenses.

Interest Income

Interest income decreased by $562,224 or 67.3% to $273,059 from $835,283 in the prior comparable period. The decrease was driven by a reduction in interest earned on U.S. Treasuries and money market instruments.

Liquidity and Capital Resources

Sources of Liquidity

From our inception up until our December 2020 IPO, we funded our operations primarily through private, state and federal contracts and grants. In October 2024, the Company raised approximately $110 million in gross proceeds from its October 2024 Offering.

On February 1, 2024, the Company entered into an ATM with H.C. Wainwright & Co., LLC as sales agent (the "Agent"), pursuant to which the Company may, from time to time, issue and sell shares of its common stock, in an aggregate offering price of up to $5.7 million through the Agent. Under the terms of the ATM, the Agent may sell the shares of common stock at market prices by any method that is deemed to be an "at the market offering" as defined in Rule 415 under the Securities Act. On May 20, 2024, the Company reduced the aggregate offering price to $50,000, not including the shares of common stock previously sold. As of September 30, 2024, 315,338 Shares have been sold under the ATM Agreement with net proceeds of $820,509 to the Company.

As at September 30, 2024, the Company had cash and cash equivalents of $913,420 and marketable securities of $2,330,226 which does not include the gross proceeds of approximately $110 million from the October 2024 Offering.

The Company has incurred recurring losses and at September 30, 2024 had an accumulated deficit of $82,288,034.

Future Funding Requirements

To date, we have not generated any revenue from the sale of commercial products. We do not expect to generate any significant revenue from product sales unless and until we obtain regulatory approval of and successfully commercialize any of our product candidates and we do not know when, or if, this will occur. We expect to continue to incur significant losses for the foreseeable future, and we expect the losses to increase as we continue the development of, and seek regulatory approvals for, our product candidates, and begin to commercialize any future approved products. We are subject to all of the risks typically related to the development of new product candidates, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. We anticipate that we will need substantial additional funding in connection with our continuing operations.

Until we can generate a sufficient amount of revenue from the commercialization of our product candidates, if ever, we expect to finance our incremental cash needs through a combination of equity offerings, debt financings, working capital lines of credit, grant funding and potential licenses and collaboration agreements. Additional working capital may not be available on commercially reasonable terms, if at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, reduce or discontinue the development or commercialization of one or more of our product candidates. If we raise additional funds through the issuance of additional debt or equity securities, it could result in dilution to our existing stockholders, increased fixed payment obligations and the existence of securities with rights that may be senior to those of our common stock. If we incur indebtedness, we could become subject to covenants that would restrict our operations and potentially impair our competitiveness, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. Additionally, any future collaborations we enter into with third parties may provide capital in the near term but limit our potential cash flow and revenue in the future. Any of the foregoing could have a material adverse effect on our business, financial condition and results of operations.

Since our inception, we have incurred significant losses and negative cash flows from operations. We have an accumulated deficit of $82,288,034 at September 30, 2024. We expect to incur substantial additional losses in the future as we conduct and expand our research and development activities.

We may seek to fund our operations through public equity or private equity or debt financings, as well as other sources. However, we may be unable to raise additional working capital, or if we are able to raise additional working capital, we may be unable to do so on commercially favorable terms. Our failure to raise capital or enter into such other arrangements if and when needed would have a negative impact on our business, results of operations and financial condition and our ability to continue to develop our product candidates.

We believe that our existing cash, cash equivalents and marketable securities as of September 30, 2024 and the gross proceeds of approximately $110 million the Company raised in October 2024, will enable us to fund our operating requirements for at least the next twelve months. However, we have based these estimates on assumptions that may prove to be wrong, and we could deplete our working capital sooner than planned.

The timing and amount of our operating expenditures will depend largely on:

- the timing and progress of preclinical and clinical development activities;
- the number and scope of preclinical and clinical programs we decide to pursue;
- possible delays or interruptions to preclinical studies, clinical trials, our receipt of services from our third-party service providers on whom we rely;
- the progress of the development efforts of third parties with whom we have entered into license and collaboration agreements;
- our ability to maintain our current research and development programs and to establish new research and development, license or collaboration arrangements;
- our ability and success in securing manufacturing relationships with third parties or, in the future, in establishing and operating a manufacturing facility;
- the costs involved in prosecuting, defending and enforcing patent claims and other intellectual property claims;
- the cost and timing of regulatory approvals;

•our efforts to enhance operational, financial and information management systems and hire additional personnel, including personnel to support development of our product candidates; and

•the costs and ongoing investments to in-license and/or acquire additional technologies.

A change in the outcome of any of these or other variables with respect to the development of any of our product candidates could significantly change the costs and timing associated with the development of that product candidate. Furthermore, our operating plans may change in the future, and we may need additional funds to meet operational needs and capital requirements associated with such operating plans.

Cash Flows

The following table sets forth a summary of the primary sources and uses of cash for each of the periods presented below:

	Nine Months Ended September 30,	
	2024	**2023**
Net cash used in operating activities	$ (13,802,492)	$ (14,642,612)
Net cash provided by investing activities	1,757,524	13,772,261
Net cash provided by financing activities	3,793,209	8,543,107
Net (decrease) increase in cash and cash equivalents	$ (8,251,759)	$ 7,672,756

Net Cash Flows Used in Operating Activities

Net cash flows used in operating activities for the nine months ended September 30, 2024, totaled $13,802,492, and consisted primarily of a net loss of $15.4 million adjusted for non-cash stock compensation of $0.2 million, a decrease in prepaid research and development of $0.1 million, an increase in accounts payable of $1.3 million, and a decrease in accrued expenses and other current liabilities of $0.1 million.

Net cash flows used in operating activities for the nine months ended September 30, 2023, totaled $14,642,612, and consisted primarily of a net loss of $14.9 million adjusted for non-cash stock compensation of $0.4 million, depreciation and lease expense of $0.2 million, decrease in prepaid expenses and other assets of $0.2 million, increase in prepaid research and development of $0.8 million, decrease in accounts payable of $0.4 million, and a decrease in accrued expenses and other current liabilities of $0.5 million.

Cash Provided by Investing Activities

Net cash flows provided by investing activities for the nine months ended September 30, 2024, totaled $1,757,524, of which $10.3 million was used for the purchase of marketable securities investments and $12.1 million was provided by maturity of marketable securities.

Net cash flows provided by investing activities for the nine months ended September 30, 2023, totaled $13,772,261, of which $20.6 million was used for the purchase of marketable securities investments and $34.4 million was provided by maturity of marketable securities.

Cash Provided by Financing Activities

Net cash flows provided by financing activities for the nine months ended September 30, 2024, totaled $3,793,209, which consisted of $3.8 million of net proceeds from issuance of common stock and pre-funded warrants in connection with our May 2024 Offering and our ATM Offering.

Net cash flows provided by financing activities for the nine months ended September 30, 2023, totaled $8,543,037, which consisted of net proceeds from issuance of common stock and pre-funded warrants in connection with our January 2023 Offering.

Off-Balance Sheet Arrangements

We have not entered into any off-balance sheet arrangements.

Contractual Obligations and Commitments

On April 18, 2022, the Company entered into an operating lease agreement through September 30, 2025 for its office space in Lexington, Massachusetts. The Lexington lease contains escalating payments during the lease period. Upon execution of this lease agreement, the Company prepaid one month of rent, applied to the first month's rent, and a security deposit, which will be held in escrow and credited at the termination of the lease. Our total lease obligation is $153,288, consisting of minimum annual rental obligations of $38,322 for fiscal year 2024 and $114,966 for fiscal year 2025.

Critical Accounting Policies and Significant Judgments and Estimates

This discussion and analysis of our financial condition and results of operations is based on our unaudited condensed consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States, or US GAAP. The preparation of these unaudited condensed consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the unaudited condensed consolidated financial statements, as well as the reported expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. While our significant accounting policies are described in more detail in the notes to our unaudited condensed consolidated financial statements included elsewhere in this Report, we believe that the following accounting policies are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates.

Research and Development Expenses

We record research and development expenses to operations as incurred. Research and development expenses represent costs incurred by us for the discovery and development of our product candidates and the development of our RAMP™ drug discovery program and prodrug technologies and include: employee-related expenses, such as salaries, benefits, travel and non-cash stock-based compensation expense; external research and development expenses incurred under arrangements with third parties, such as CROs, preclinical testing organizations, clinical testing organizations, CMOs, academic and non-profit institutions and consultants; costs to acquire technologies to be used in research and development that have not reached technological feasibility and have no alternative future use; license fees; and other expenses, which include direct and allocated expenses for laboratory, facilities and other costs.

As part of the process of preparing financial statements, we are required to estimate and accrue expenses. A portion of our research and development expenses is comprised of external costs, which we track on a program-specific basis. We record the estimated expenses of research and development activities conducted by third-party service providers as they are incurred and provided within research and development expense in the condensed consolidated statements of operations and comprehensive loss. These services include the conduct of clinical studies, preclinical studies and consulting services. These costs are a significant component of our research and development expenses.

Costs for research and development activities are recognized based on costs incurred. We make significant judgments and estimates in determining the accrued balance in each reporting period. As actual costs become known, we adjust our accrued estimates. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed may vary from our estimates and could result in us reporting amounts that are too high or too low in any particular period. Our accrued expenses are dependent, in part, upon the receipt of timely and accurate reporting from external clinical research organizations and other third-party service providers. Due to the nature of estimates, we cannot assure you that we will not make changes to our estimates in the future as we become aware of additional information about the status or conduct of our clinical trials and other research activities.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

As a smaller reporting company, we are not required to provide disclosure regarding quantitative and qualitative market risk.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we evaluated the effectiveness of the design and operation of our disclosure controls and procedures pursuant to Rule 13a-15(b) and 15d-15(b) under the Exchange Act as of the end of the period covered by this Report. Our disclosure controls and procedures are designed to ensure that information required to be disclosed in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including the Chief Executive Officer and the Chief Financial Officer, to allow timely decisions regarding required disclosures. Any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objective and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were effective at a reasonable assurance level as of September 30, 2024.

Changes in Internal Control over Financial Reporting

During the quarter ended June 30, 2024, we previously disclosed a material weakness in our internal control over financial reporting related to a certain non-routine transaction. To address this material weakness, we strengthened our internal controls to ensure all aspects of accounting treatment and disclosure are evaluated as part of non-routine accounting transactions.

As a result of the remediation activities taken and controls in place at September 30, 2024, we have remediated this previously disclosed material weakness.

Other than as described above, there were no changes in our internal control over financial reporting or in any other factors that could significantly affect these controls during the three and nine months ended September 30, 2024 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

As previously disclosed, on April 26, 2024, the Company received a notice of a demand for arbitration with the American Arbitration Association from Pivot Holding LLC ("Pivot"), a successor in interest to Sphaera Pharma Pte. Ltd. ("Sphaera"), in connection with the Collaborative Research and Development Agreement dated February 29, 2012, as amended, between the Company and Sphaera (the "Collaboration Agreement"), alleging breach of contract by the Company for failure to pay certain milestone payments under the Collaboration Agreement and seeking damages. Also as previously disclosed, on June 17, 2024, the Company filed an answering statement and counterclaim denying that it had breached the Collaboration Agreement and counterclaiming. On September 30, 2024, following a non-binding confidential mediation, the Company and Pivot entered into a settlement agreement (the "Settlement Agreement") pursuant to which the Company agreed to pay to Pivot a total sum of $500,000, which Pivot agreed shall constitute full and complete payment for, and shall fully satisfy, any and all amounts for any and all project milestone payments owed or that may be owed to Sphaera and/or Pivot by the Company under the Collaboration Agreement for: (i) "First dosing of patient in US phase 1 trial"; (ii) "US Phase 1 trial completion with endpoints met"; and (iii) "US Phase 2 trial completion with endpoints met" (each as described in the Collaboration Agreement) which payments would have totaled $1.625 million in the event Pivot were to be successful in claiming that the Company conducted Phase 1 and Phase 2 trials or that would be due upon successful milestones in the future. The Company also agreed to pay to Pivot a one-time payment of $4.4 million, increased from $4.0 million, upon FDA Approval (as described in the Collaboration Agreement) and the parties agreed that no further FDA Approval milestone payment(s) shall be due to Pivot in the event that the Company receives additional FDA Approval(s). The Settlement Agreement contains customary mutual releases and covenants not to sue. Except as otherwise provided in the Settlement Agreement, all terms in the Collaboration Agreement shall remain in full force and effect.

Item 1A. Risk Factors.

Our focus on IkT-001 Pro as a treatment for PAH may not prove successful.

It is possible that IkT-001Pro may not improve the side effect profile for the treatment of PAH compared to imatinib mesylate or may not be effective as an add-on treatment for PAH. There can be no assurance that the Company's clinical trial in PAH for IkT-001Pro will be successful and even if successful that IkT-001Pro will be approved by the FDA for PAH or achieve marketplace success.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

Exhibit No.	Filed Exhibit Description	Incorporated by Reference to SEC Filing			
		Form	Exhibit No.	File No.	Date Filed
3.1	Amended and Restated Certificate of Incorporation of Inhibikase Therapeutics, Inc., as most recently amended and restated effective Wednesday, December 23, 2020.	8-K	3.1	001-39676	12/29/2020
3.2	Certificate of Amendment to Amended and Restated Certificate of Incorporation of Inhibikase Therapeutics, Inc.	8-K	3.1	001-39676	06/29/2023
3.3	Amended and Restated Bylaws of Inhibikase Therapeutics, Inc.	8-K	3.3	001-39676	12/29/2020
4.1	Form of Pre-Funded Warrant (October 2024)	8-K	4.1	001-39676	10/10/2024
4.2	Form of Series A-1 Warrant (October 2024)	8-K	4.2	001-39676	10/10/2024
4.3	Form of Series B-1 Warrant (October 2024)	8-K	4.3	001-39676	10/10/2024
10.1	Securities Purchase Agreement, dated as of October 9, 2024	8-K	10.1	001-39676	10/10/2024
10.2	Form of Registration Rights Agreement	8-K	10.2	001-39676	10/10/2024
10.3	Form of Support Agreement	8-K	10.3	001-39676	10/10/2024
10.4#	Form of Director Offer Letter	8-K	10.4	001-39676	10/10/2024
10.5	Settlement Agreement, dated as of September 30, 2024	8-K	10.5	001-39676	10/10/2024
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
32.1**	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
32.2**	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
101.INS	Inline XBRL Instance Document				
101.SCH	Inline XBRL Taxonomy Extension Schema Document				
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document				
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document				
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document				
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document				
104	Cover Page Interactive Data File (formatted as inline XBRL with applicable taxonomy extension information contained in Exhibits 101)				

* Filed herewith.

** Furnished herewith.

A contract, compensatory plan or arrangement to which a director or executive officers is a party or in which one or more directors or executive officers are eligible to participate.

Exhibits 32.1 and 32.2 are being furnished and shall not be deemed to be “filed” for purposes of Section 18 of the Exchange Act or otherwise subject to the liability of that section, nor shall such exhibits be deemed to be incorporated by reference in any registration statement or other document filed under the Securities Act or the Exchange Act, except as otherwise stated in any such filing.

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 thereunto duly authorized.

Inhibikase Therapeutics, Inc.

Date: November 14, 2024 By: /s/ MILTON H. WERNER, Ph.D.
Milton H. Werner, Ph.D.
Chief Executive Officer
(Principal Executive Officer)

Date: November 14, 2024 By: /s/ GARTH LEES-ROLFE
Garth Lees-Rolfe
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

EXHIBIT 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Milton H. Werner, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Inhibikase Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ Milton H. Werner

Milton H. Werner, Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)
Date: November 14, 2024

EXHIBIT 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Garth Lees-Rolfe, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Inhibikase Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ Garth Lees-Rolfe

Garth Lees-Rolfe
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)
Date: November 14, 2024

EXHIBIT 32.1

CERTIFICATION OF
PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Inhibikase Therapeutics, Inc. (the "Company") for the period ended September 30, 2024 (the "Report"), the undersigned hereby certifies in his capacity as President and Chief Executive Officer of the Company pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

1. the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2. the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: November 14, 2024

By: /s/ Milton H. Werner
Milton H. Werner, Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 32.2

CERTIFICATION OF
PRINCIPAL FINANCIAL OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Inhibikase Therapeutics, Inc. (the "Company") for the period ended September 30, 2024 (the "Report"), the undersigned hereby certifies in his capacity as Chief Financial Officer of the Company pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

1. the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2. the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: November 14, 2024

By: /s/ Garth Lees-Rolfe
Garth Lees-Rolfe
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)