

**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, 2022

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
(State or other jurisdiction of
incorporation or organization)
3350 Riverwood Parkway SE, Suite 1900
Atlanta, GA
(Address of principal executive offices)

26-3407249
(I.R.S. Employer
Identification No.)

30339
(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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input checked="" type="checkbox"/>

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, 2022, the registrant had 25,227,051 shares of common stock, \$0.001 par value per share, outstanding.

Table of Contents

	Page
PART I.	
Item 1.	
FINANCIAL INFORMATION	
Condensed Consolidated Financial Statements (Unaudited)	1
Condensed Consolidated Balance Sheets as of September 30, 2022 (Unaudited) and December 31, 2021	1
Condensed Consolidated Statements of Operations and Comprehensive Loss for the Three and Nine Months Ended September 30, 2022 and 2021 (Unaudited)	2
Condensed Consolidated Statements of Stockholders' Equity for the Three and Nine Months Ended September 30, 2022 and 2021 (Unaudited)	3
Condensed Consolidated Statements of Cash Flows for the Nine Months Ended September 30, 2022 and 2021 (Unaudited)	4
Notes to Unaudited Condensed Consolidated Financial Statements	5
Item 2.	15
Item 3.	26
Item 4.	26
PART II.	
OTHER INFORMATION	
Item 1.	27
Item 1A.	27
Item 2.	27
Item 3.	27
Item 4.	27
Item 5.	27
Item 6.	28
Signatures	29

PART I—FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements (Unaudited).

Inhibikase Therapeutics, Inc.
Condensed Consolidated Balance Sheets

	September 30, 2022 (unaudited)	December 31, 2021 (Note 3)
Assets		
Current assets:		
Cash and cash equivalents	\$ 5,781,918	\$ 40,750,133
Marketable securities	20,752,290	—
Accounts receivable	13,842	110,141
Prepaid research and development	932,419	107,000
Prepaid expenses and other current assets	505,924	1,502,725
Total current assets	27,986,393	42,469,999
Equipment and improvements, net	241,574	—
Right-of-use asset	353,250	—
Total assets	<u>\$ 28,581,217</u>	<u>\$ 42,469,999</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 781,223	\$ 1,089,778
Lease obligation, current	142,048	—
Accrued expenses and other current liabilities	2,289,726	2,715,761
Notes payable	—	248,911
Total current liabilities	3,212,997	4,054,450
Lease obligations	232,020	—
Total liabilities	3,445,017	4,054,450
Commitments and contingencies (see Note 15)		
Stockholders' equity:		
Preferred stock, \$0.001 par value; 10,000,000 shares authorized; 0 shares issued and outstanding at September 30, 2022 and December 31, 2021	—	—
Common stock, \$0.001 par value; 100,000,000 shares authorized; 25,227,051 and 25,155,198 shares issued and outstanding at September 30, 2022 and December 31, 2021, respectively	25,227	25,155
Additional paid-in capital	68,676,935	68,208,081
Accumulated other comprehensive income	26,828	—
Accumulated deficit	(43,592,790)	(29,817,687)
Total stockholders' equity	25,136,200	38,415,549
Total liabilities and stockholders' equity	<u>\$ 28,581,217</u>	<u>\$ 42,469,999</u>

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,	
	2022	2021	2022	2021
Revenue:				
Grant revenue	\$ 7,291	\$ 328,459	\$ 59,874	\$ 3,098,661
Total revenue	7,291	328,459	59,874	3,098,661
Costs and expenses:				
Research and development	2,981,653	3,154,553	8,980,827	7,968,846
Selling, general and administrative	1,538,737	1,644,946	4,872,681	4,854,494
Total costs and expenses	4,520,390	4,799,499	13,853,508	12,823,340
Loss from operations	(4,513,099)	(4,471,040)	(13,793,634)	(9,724,679)
Interest income	18,536	—	18,536	—
Interest expense	—	157	5	19,765
Net loss	\$ (4,494,563)	\$ (4,471,197)	\$ (13,775,103)	\$ (9,744,444)
Other comprehensive income:				
Unrealized gains on marketable securities	26,828	—	26,828	—
Comprehensive loss	\$ (4,467,735)	\$ (4,471,197)	\$ (13,748,275)	\$ (9,744,444)
Net loss per share – basic and diluted	\$ (0.18)	\$ (0.18)	\$ (0.55)	\$ (0.61)
Weighted-average number of common shares – basic and diluted	25,227,051	25,143,559	25,219,931	15,868,421

See accompanying notes to condensed consolidated financial statements.

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

Common Stock

	Shares	Amount	Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
Balance at December 31, 2021	25,155,198	\$ 25,155	\$ 68,208,081	\$ —	\$ (29,817,687)	\$ 38,415,549
Stock-based compensation expense	—	—	123,229	—	—	123,229
Issuance of common stock for services	50,000	50	66,950	—	—	67,000
Issuance of common stock, stock options exercised	21,853	22	44,120	—	—	44,142
Net loss	—	—	—	—	(4,640,601)	(4,640,601)
Balance at March 31, 2022	25,227,051	\$ 25,227	\$ 68,442,380	\$ —	\$ (34,458,288)	\$ 34,009,319
Stock-based compensation expense	—	—	132,767	—	—	132,767
Net loss	—	—	—	—	(4,639,939)	(4,639,939)
Balance at June 30, 2022	<u>25,227,051</u>	<u>\$ 25,227</u>	<u>\$ 68,575,147</u>	<u>\$ —</u>	<u>\$ (39,098,227)</u>	<u>\$ 29,502,147</u>
Stock-based compensation expense	—	—	101,788	—	—	101,788
Other comprehensive income	—	—	—	26,828	—	26,828
Net loss	—	—	—	—	(4,494,563)	(4,494,563)
Balance at September 30, 2022	<u>25,227,051</u>	<u>\$ 25,227</u>	<u>\$ 68,676,935</u>	<u>\$ 26,828</u>	<u>\$ (43,592,790)</u>	<u>\$ 25,136,200</u>

Common Stock

	Shares	Amount	Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
Balance at December 31, 2020	10,050,849	\$ 10,051	\$ 24,805,929	\$ (15,031,624)	\$ 9,784,356
Stock-based compensation expense	—	—	591,124	—	591,124
Warrant expense	—	—	237,768	—	237,768
Issuance of common stock	9,000	9	60,382	—	60,391
Net loss	—	—	—	(2,637,068)	(2,637,068)
Balance at March 31, 2021	10,059,849	\$ 10,060	\$ 25,695,203	\$ (17,668,692)	\$ 8,036,571
Stock-based compensation expense	—	—	322,483	—	322,483
Warrant expense	—	—	239,415	—	239,415
Issuance of common stock, follow on offering	15,000,000	15,000	41,120,357	—	41,135,357
Issuance of common stock, stock options exercised	73,496	74	(43,369)	—	(43,295)
Net loss	—	—	—	(2,636,179)	(2,636,179)
Balance at June 30, 2021	<u>25,133,345</u>	<u>\$ 25,134</u>	<u>\$ 67,334,089</u>	<u>\$ (20,304,871)</u>	<u>\$ 47,054,352</u>
Stock-based compensation expense	—	—	352,419	—	352,419
Warrant expense	—	—	181,762	—	181,762
Issuance of common stock, cashless warrant exercise	21,853	21	44,122	—	44,143
Net loss	—	—	—	(4,471,197)	(4,471,197)
Balance at September 30, 2021	<u>25,155,198</u>	<u>\$ 25,155</u>	<u>\$ 67,912,392</u>	<u>\$ (24,776,068)</u>	<u>\$ 43,161,479</u>

See accompanying notes to condensed consolidated financial statements.

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

	Nine Months Ended September 30,	
	2022	2021
Operating activities		
Net loss	\$ (13,775,103)	\$ (9,744,444)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	1,681	—
Stock-based compensation expense	357,784	1,266,026
Noncash lease expense	20,818	—
Noncash consulting fees	67,000	60,391
Noncash PPP loan forgiveness	—	(27,550)
Warrant expense	—	658,945
Changes in operating assets and liabilities:		
Grants receivable	96,299	(217,482)
Prepaid expenses and other current assets	996,801	(486,551)
Prepaid research and development	(825,419)	509,975
Accounts payable	(308,555)	(1,166,879)
Accrued expenses and other current liabilities	(449,718)	1,272,076
Deferred revenue	23,683	(2,325,741)
Net cash used in operating activities	(13,794,729)	(10,201,234)
Investing activities		
Purchases of investments - marketable securities	(20,725,462)	—
Purchases of equipment and improvements	(243,255)	—
Net cash used in investing activities	(20,968,717)	—
Financing activities		
Proceeds from issuance of common stock	—	41,135,357
Issuance of common stock from exercise of stock options	44,142	78,500
Payment of employee taxes in connection with stock option exercise	—	(77,652)
Repayments of notes payable	(248,911)	(42,534)
Net cash (used in) provided by financing activities	(204,769)	41,093,671
Net (decrease) increase in cash and cash equivalents	(34,968,215)	30,892,437
Cash and cash equivalents at beginning of period	40,750,133	13,953,513
Cash and cash equivalents at end of period	\$ 5,781,918	\$ 44,845,950
Supplemental disclosures of cash flow information		
Cash paid for interest	\$ 973	\$ 19,608
Non-cash financing activities		
PPP loan forgiveness	\$ —	\$ 27,550

See accompanying notes to condensed consolidated financial statements.

Inhibikase Therapeutics, Inc.
Notes to Unaudited Condensed Consolidated Financial Statements

1. Nature of Business

Inhibikase Therapeutics, Inc. (the "Company," "we" or "our") is a clinical-stage pharmaceutical company developing therapeutics for Parkinson's disease, or PD, and related disorders. The Company's multi-therapeutic pipeline has a primary focus on neurodegeneration and its lead program IKT-148009, an Abelson Tyrosine Kinase (c-Abl) inhibitor, targets the treatment of Parkinson's disease inside and outside the brain as well as other diseases that arise from Abelson Tyrosine Kinases. In 2021, we commenced clinical development of IKT-148009, a small molecule Abelson Tyrosine Kinase inhibitor we believe can modify the course of Parkinson's disease including its manifestation in the gastrointestinal tract, or GI. The U.S. Food and Drug Administration ("FDA") review of the Phase 1/1b data and the protocol for the Phase 2a three-month dosing study resulted in the FDA agreeing with the Company's view that it was appropriate for the Phase 2a study to begin, prompting the Company to initiate the Phase 2 study, the 201 trial, at the end of May 2022. We have opened 16 of 34 selected sites as of November 1, 2022, and 11 patients have randomized into the trial of 120 patients planned to be enrolled, with no serious adverse events observed to date. In October 2022, an Investigational New Drug Application ("IND") to expand use of IKT-148009 into the Parkinson's-related disease Multiple System Atrophy ("MSA") was filed with the FDA. In November 2022, following review of the IND for IKT-148009 as a treatment for MSA, the FDA notified the Company that it was placing the IKT-148009 programs for Parkinson's disease and MSA on clinical hold. The FDA indicated it will provide an official clinical hold letter to Inhibikase within 30 days to explain the basis of this decision.

The Company is also developing platform technologies for alternate ways to deliver protein kinase inhibitors in patients. Our first example of this technology is IKT-001Pro, a prodrug of the anticancer agent imatinib mesylate to treat Stable phase Chronic Myelogenous Leukemia ("SP CML"). Pursuant to its IND which was cleared by the FDA in August 2022, IKT-001Pro will be evaluated in a two-part dose finding/dose equivalence study in up to 56 healthy volunteers. The study is designed to evaluate the steady-state pharmacokinetics of IKT-001Pro and determine the dose of IKT-001Pro equivalent to 400 mg imatinib mesylate, the standard-of-care dose for SP-CML. Following the study, Inhibikase will confer with the FDA and seek agreement on the requirements for the New Drug Application ("NDA") process following the proposed approval path for IKT-001Pro under the 505(b)(2) statute. The Company will simultaneously pursue a superiority study comparing the selected doses of IKT-001Pro to standard-of-care 400 mg imatinib mesylate in SP-CML patients using a novel, two-period-wait-list-crossover-switching study.

2. Liquidity

The Company has recognized recurring losses. At September 30, 2022, the Company had working capital of \$24,773,396, an accumulated deficit of \$43,592,790, cash of \$5,781,918, marketable securities of \$20,752,290 and accounts payable, accrued expenses and other current liabilities of \$3,070,949. The Company had active grants in the amount of \$385,888, of which \$300,386 remained available in accounts held by the U.S. Treasury as of November 1, 2022.

The future success of the Company is dependent on its ability to have the FDA lift the clinical hold on the Company's IKT-148009 programs for PD and MSA, successfully obtain additional working capital, obtain regulatory approval for and successfully launch and commercialize its product candidates and to ultimately attain profitable operations. Prior to its initial public offering in December 2020 ("IPO"), the Company had funded its operations primarily through cash received in connection with revenue from its various grant programs. In addition, in June 2021 and December 2020, the Company raised approximately \$41.1 million and \$14.6 million in working capital from its underwritten public offering (the "June 2021 Offering") and its initial public offering IPO, respectively.

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 and general and administrative expenses related to its product candidate programs. 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 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 working capital at September 30, 2022 is sufficient to fund its normal operations through February 2024. However, until the Company receives and evaluates the official clinical hold letter from the FDA, it is unable to fully evaluate the effect of the clinical hold on the Company's liquidity. For example, if or when the clinical hold is lifted by the FDA, it is likely that the Company will have to recommence its IKT-148009 201 clinical trial for PD. In such event, the costs of completion of such clinical trial will be greater than originally anticipated.

The accompanying unaudited 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, 2021 balance sheet was derived from December 31, 2021 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, 2022. The condensed unaudited 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, 2021 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 Updates ("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 US 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 its assertions made in connection with its assessment of liquidity and working capital adequacy, of 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.

Concentrations of Credit Risk

For the three and nine months ended September 30, 2022 and 2021, the Company derived more than 90% 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. 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.

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 balance sheet. Under the standard, disclosure of key information about leasing arrangements to assist users of the 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.

	<u>Estimated Useful Economic Life</u>
Leasehold property improvements, right of use assets	Lesser of lease term or useful life
Furniture and office equipment	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, which include cash equivalents and marketable securities, 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 and improvements are stated at cost, less accumulated depreciation.

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 balance sheet. Available-for-sale debt securities are carried at fair value with unrealized gains and losses reported as a component of stockholders' 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, 2022:

Assets	Fair Value Measurements as of September 30, 2022 Using:			
	Level 1	Level 2	Level 3	Total
U.S. Treasury obligations	\$ 20,752,290	\$ —	\$ —	\$ 20,752,290
Total	<u>\$ 20,752,290</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 20,752,290</u>

There were no marketable securities as of December 31, 2021.

5. Marketable Securities

Marketable securities consisted of the following at September 30, 2022:

September 30, 2022	Amortized Cost	Unrealized Gain	Unrealized Loss	Fair Value
Marketable securities, available-for-sale:				
U.S. Treasury obligations	\$ 20,725,462	\$ 50,836	\$ (24,008)	\$ 20,752,290
Total	<u>\$ 20,725,462</u>	<u>\$ 50,836</u>	<u>\$ (24,008)</u>	<u>\$ 20,752,290</u>

As of September 30, 2022, the Company held two U.S. Treasury debt securities that were in an unrealized gain position totaling \$50,836 and two U.S. Treasury debt securities that were in an unrealized loss position totaling \$24,008. There were no marketable securities as of December 31, 2021.

6. Equipment and Improvements

Equipment and Improvements, net

	September 30, 2022	
Furniture and office equipment	\$	72,692
Lab equipment		153,668
IT equipment		16,895
		243,255
Less: Accumulated Depreciation		1,681
Total	\$	<u>241,574</u>

7. Supplemental Balance Sheet Information

Accrued expenses and other current liabilities consist of the following:

	September 30, 2022	December 31, 2021
Accrued consulting	\$ 229,661	\$ 210,000
Accrued compensation	417,573	421,734
Deferred revenue	23,683	—
Accrued research and development	1,586,138	2,077,932
Accrued interest	—	968
Accrued other	32,671	5,127
Total accrued expenses and other current liabilities	<u>\$ 2,289,726</u>	<u>\$ 2,715,761</u>

8. Notes Payable

Notes payable outstanding were \$0 and \$248,911 at September 30, 2022 and December 31, 2021, respectively.

Note Payable to CEO

On February 5, 2020 (the "Issue Date"), the Company issued a note payable to its CEO (the "CEO Note") in the face amount of \$245,250 bearing 1.59% APR simple interest in exchange for cash. The net proceeds of \$245,250 were used as working capital by the Company. The note carried an original maturity of the earlier of the sixth month following the Issue Date or the date the Company has sufficient funds to repay the CEO Note. If an event of default occurred and continued, the Company agreed to issue a warrant to the holder with a strike price of \$4.87 per share for a number of shares equal to 150% of the value of the loan. The Company assessed the terms and features of the CEO Note and determined that none of the terms and features represented embedded derivatives that require bifurcation.

On June 13, 2020, the holder of the CEO Note and the Company entered into a restated agreement (the "CEO Restated Note"). The CEO Restated Note in the amount of \$248,911 extended the stated maturity date of the CEO Note from the earlier of the sixth month following the (original) Issue Date or the date the Company has sufficient funds to repay the note to the earlier of the 30th month following the (original) Issue Date or the date the Company has sufficient funds to repay the CEO Restated Note. The Issue Date, February 5, 2020, remained unchanged. In addition, the interest rate was reduced, effective as of the Issue Date, from 1.59% APR to 0.25%. The CEO Restated Note also changed the exercise price of the warrant from \$4.87 to \$4.81 per share in the case of any default. The other provisions of the CEO Restated Note remained the same, in all material respects, to the CEO Note. The Company and its CEO agreed that the CEO Restated Note would not be repaid for a minimum of 12 months following the closing of its initial public offering. The principal balance of the CEO Note was \$248,911 at December 31, 2021. The principal balance plus accrued and unpaid interest on the CEO Note were settled in full, without adjustment, in cash on January 3, 2022.

9. Stockholders' Equity

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, 2022, a total of 5,589,991 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") and the 2011 Equity Incentive Plan.

Share Issuances

In March 2021, a corporate accredited investor subscribed for, and the Company issued, 9,000 shares of its common stock in exchange for consulting services. The fair value of the common stock was \$60,391 based upon the closing price of the shares on the date of the transaction. Issuance costs were not material. No additional rights or options were granted to this accredited investor in connection with this issuance. The \$60,391 fair value was a component of selling, general and administrative costs for the nine months ended September 30, 2021.

In connection with the June 2021 Offering, the Company issued and sold 15,000,000 fully paid non-assessable shares of its common stock at a public offering price of \$3.00 per share. Proceeds from the June 2021 Offering were \$41.1 million after deducting offering costs, underwriting discounts and commissions of approximately \$3.9 million.

In January 2022, the Company issued 21,853 shares of its common stock in connection with the exercise of non-qualified stock options with a strike price of \$2.02 per share. Issuance costs were not material. No additional rights or options were granted to this accredited investor in connection with this issuance. This issuance was exempt from registration pursuant to Section 4(a)(2) of the Securities Act as transactions by an issuer not involving any public offering.

In February 2022, a corporate accredited investor subscribed for, and the Company issued, 50,000 shares of its common stock in exchange for consulting services. The fair value of the common stock was \$67,000 based upon the closing price of the shares on the date of the transaction. Issuance costs were not material. No additional rights or options were granted to this accredited investor in connection with this issuance. This issuance was exempt from registration pursuant to Section 4(a)(2) of the Securities Act as transactions by an issuer not involving any public offering.

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, 2022, the Company granted 160,000 options to purchase its common stock to each of the members of its board of directors with a strike price of \$0.81 per share and an aggregate grant date fair value of \$82,492. The options will cliff vest on the sooner to occur of one year from the June 24, 2022 grant date or the day prior to the 2023 annual meeting. On September 1, 2022, 40,000 of the 160,000 options were forfeited in connection with the resignation of a board member. The Company reversed prior stock compensation expense of \$339 in connection with the forfeiture.

During the nine months ended September 30, 2022, the Company granted 239,887 options to purchase its common stock to certain employees. The employee grants will vest on each anniversary in equal parts over three years. The weighted average strike price and the aggregate grant date fair value of these options is \$1.07 and \$165,563, respectively.

During the nine months ended September 30, 2022, 29,322 employee options were forfeited in connection with termination of employment. The Company reversed \$8,399 of prior stock compensation expense in connection with this forfeiture.

In addition, on September 1, 2022, the Company awarded an initial grant of 60,000 options to purchase common stock to a new member of the board of directors. This award will vest 50% on each of the first two anniversaries of the award. The strike price and fair value of this award is \$0.95 and \$37,225, respectively.

During the nine months ended September 30, 2021, the Company granted 68,628 options to purchase common stock to its scientific advisory board members with a strike price of \$6.82 per share, vesting immediately, with an aggregate grant date fair value of \$259,674.

On June 25, 2021, the Company granted a total of 90,708 options to members of its board of directors with a strike price of \$2.92 per share, vesting one year from the date of the grant, with an aggregate grant date fair value of \$160,000.

On August 16, 2021, the Company granted 27,240 employee stock options with a strike price of \$1.79 per share, vesting in three equal annual installments commencing on the first anniversary of the grant date, with a grant date fair value of \$50,000.

Stock-Based Compensation Expense

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

	Nine Months Ended September 30,	
	2022	2021
Research and development	\$ 98,722	\$ 592,966
Selling, general and administrative	259,062	673,060
Total stock-based compensation expense	<u>\$ 357,784</u>	<u>\$ 1,266,026</u>

11. Warrants

The Company recognized \$181,762 and \$658,945 in warrant expense for the three and nine months ended September 30, 2021, respectively, included in selling, general and administration expense.

12. ATM Program

On May 16, 2022, the Company entered into an Equity Distribution Agreement (the "Agreement") with Piper Sandler & Co. 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 \$9.8 million (the "Shares") through the Agent. Under the terms of the Agreement, the Agent may sell the Shares 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, as amended.

Subject to the terms and conditions of the 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 Agreement or terminate the 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 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, 2022, no Shares have been sold under the Agreement.

13. Net Loss Per Share

The following table presents the calculation of basic and diluted net loss per share applicable to common stockholders:

	Nine Months Ended September 30,	
	2022	2021
Numerator:		
Net loss	<u>\$ (13,775,103)</u>	<u>\$ (9,744,444)</u>
Denominator:		
Weighted-average number of common shares outstanding – basic and diluted	<u>25,219,931</u>	<u>15,868,421</u>
Net loss per share applicable to common stockholders – basic and diluted	<u>\$ (0.55)</u>	<u>\$ (0.61)</u>

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,	
	2022	2021
Options to purchase shares of stock	4,028,078	3,630,044
Warrants to purchase shares of stock	1,561,913	1,561,913
Total	<u>5,589,991</u>	<u>5,191,957</u>

14. Income Taxes

During the nine months ended September 30, 2022 and 2021, 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.

15. Commitments and Contingencies

Impact of the COVID-19 Pandemic on Our Operations

There continues to be widespread impact from the COVID-19 pandemic. Beginning in the first quarter of 2021, there has been a trend in many parts of the world of increasing availability and administration of vaccines against COVID-19, as well as an easing of restrictions on social, business, travel and government activities and functions. On the other hand, infection rates and regulations continue to fluctuate in various regions and there are ongoing global impacts resulting from the pandemic, including challenges and increases in costs for logistics and supply chains. The level and nature of the disruption caused by COVID-19 is unpredictable, may be cyclical and long-lasting and may vary from location to location.

In addition, we have experienced and are experiencing varying levels of inflation resulting in part from various supply chain disruptions, increased shipping and transportation costs, increased raw material and labor costs and other disruptions caused by the COVID-19 pandemic and general global economic conditions.

The COVID-19 pandemic has caused significant, industry-wide delays in clinical trials. There are multiple causes of these delays, including reluctance of patients to enroll or continue in trials for fear of exposure to COVID-19, local and regional shelter-in-place orders and regulations that discourage, hamper, or prohibit patient visits, healthcare providers and health systems shifting away from clinical trials toward the acute care of COVID-19 patients and the FDA and other regulators making product candidates for the treatment of COVID-19 a priority over product candidates unrelated to the pandemic.

As a result of the COVID-19 pandemic, commencement of enrollment in our clinical trials may be delayed. In addition, after enrollment in these trials, if patients contract COVID-19 during participation in the Company's trials or are subject to isolation or shelter-in-place restrictions, this may cause them to drop out of the Company's trials, miss scheduled doses or follow-up visits or otherwise fail to follow trial protocols. If patients are unable to follow the trial protocols or if the Company's trial results are otherwise affected by the consequences of the COVID-19 pandemic on patient participation or actions taken to mitigate COVID-19 spread, the integrity of data from the Company's trials may be compromised or not accepted by the FDA or other regulatory authorities, which could impact or delay a clinical development program. The Company anticipates that the COVID-19 pandemic may also impact manufacturing and distribution of materials necessary for the conductance of its clinical trials.

Although the Company did not experience a material impact on its operations during the nine months ended September 30, 2022 and 2021, the Company notes the high level of difficulty in determining the future potential adverse financial impact and other effects of COVID-19 on the Company and its programs, given the rapid and dramatic evolution in the course and impact of the pandemic and the societal and governmental response to it.

Litigation

From time to time, the Company may become involved in various lawsuits and legal proceedings which arise in the ordinary course of business. When the Company is aware of a claim or potential claim, it assesses the likelihood of any loss or exposure. If it is probable that a loss will result and the amount of the loss can be reasonably estimated, the Company will record a liability for the loss. In addition to the estimated loss, the recorded liability would include probable and estimable legal costs associated with the claim or potential claim. Litigation is subject to inherent uncertainties, and an adverse result in these or other matters may arise from time to time that may harm the Company's business.

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 July 31, 2025.

The Company accounts for the Office Lease under the provisions of ASU No. 2021-09, ASU 2018-10, and ASC 842. We recorded a right-of-use asset and a corresponding operating lease liability on the Company's condensed consolidated balance sheet 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 \$353,350 at September 30, 2022. The operating lease obligations totaled \$374,068 at September 30, 2022 of which \$142,048 is included under current liabilities and \$232,020 is included under non-current liabilities. The Company recorded lease expense of \$20,818 for the three and nine months ended September 30, 2022 included 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, 2022, 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 these leases at September 30, 2022, are presented by calendar year as follows:

Year		
2022	\$	33,469
2023		145,836
2024		150,095
2025		114,966
Total lease payments		444,366
Less: imputed interest		70,298
Present value of operating lease liabilities	\$	<u>374,068</u>

16.Subsequent Events

Minimum Bid Price of Common Stock

On July 25, 2022, the Company received a letter from the Listing Qualifications Staff of The Nasdaq Stock Market LLC ("Nasdaq") indicating that, based upon the closing bid price of the Company's common stock for the last 30 consecutive business days, the Company was not in compliance with the requirement to maintain a minimum bid price of \$1.00 per share for continued listing on The Nasdaq Capital Market (the "Minimum Bid Price Requirement"), as set forth in Nasdaq Listing Rule 5550(a)(2) (the "Minimum Bid Price Notice").

The Minimum Bid Price Notice has no immediate effect on the continued listing status of the Company's Common Stock on The Nasdaq Capital Market and, therefore, our listing remains fully effective.

The Company is provided a compliance period of 180 calendar days from the date of the Minimum Bid Price Notice, or until January 23, 2023, to regain compliance with the Minimum Bid Price Requirement, pursuant to Nasdaq Listing Rule 5810(c)(3)(A) (the "Minimum Bid Price Compliance Period"). If at any time before January 23, 2023 the closing bid price of the Company's Common Stock closes at or above \$1.00 per share for a minimum of 10 consecutive business days, Nasdaq will provide written notification that the Company has achieved compliance with the Minimum Bid Price Requirement, and the matter would be resolved. If the Company does not regain compliance during the Minimum Bid Price Compliance Period, then Nasdaq may grant the Company a second 180 calendar day period to regain compliance, provided the Company (i) meets the continued listing requirement for market value of publicly-held shares and all other initial listing standards for The Nasdaq Capital Market, other than the minimum closing bid price requirement, and (ii) notifies Nasdaq of its intent to cure the deficiency.

As of November 14, 2022, the Company had not regained compliance with the Minimum Bid Price Requirement.

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 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, 2021, as amended, and the following factors and risks:

- The initiation, timing, progress and results of our current and future preclinical studies and clinical trials and related preparatory work and the period during which the results of the trials will become available, as well as our research and development programs, including our ability to resolve the FDA's clinical holds on our INDs for IkT-148009;
- We have received notice from The Nasdaq Stock Market regarding our failure to satisfy their continued listing requirements, and as a result, we may not be able to maintain the listing of our common stock on Nasdaq;
- 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. We cannot give any assurance that any of our product candidates will receive regulatory approval, which is necessary before they can be commercialized;
- If we are unable to successfully raise additional capital, our future clinical trials and product development could be limited and our long-term viability may be threatened;
- 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; and
- Positive results from early preclinical 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. If we cannot show positive results or replicate any positive results from our earlier preclinical studies of our product candidates in our later preclinical studies and current and future clinical trials, we may be unable to successfully develop, obtain regulatory approval for and commercialize our product candidates.

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 and risk factors 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 therapeutics for Parkinson's disease, or PD, and related disorders. Our multi-therapeutic pipeline has a primary focus on neurodegeneration and our lead program IKT-148009, an Abelson Tyrosine Kinase (c-Abl) inhibitor, targets the treatment of Parkinson's disease inside and outside the brain as well as other diseases that arise from Abelson Tyrosine Kinases. In 2021, we commenced clinical development of IKT-148009, a small molecule Abelson Tyrosine Kinase inhibitor we believe can modify the course of Parkinson's disease including its manifestation in the gastrointestinal tract, or GI. Results to date of our completed Phase 1/1b Single and Multiple Ascending Dose escalation study (SAD and MAD, respectively) in older and elderly healthy volunteers and in mild to moderately advanced Parkinson's patients have revealed important insights into the safety, tolerability and pharmacokinetics of IKT-148009 in human subjects and patients. Results from the 88 older and elderly healthy Phase 1 subjects and 14 Phase 1b Parkinson's patients have shown that IKT-148009 has a half-life of greater than 24 hours and just a 25 mg once-daily oral dose reached exposures that are consistent with the exposures to the drug that resulted in therapeutic efficacy in animal models of progressive Parkinson's disease. In addition, review of unblinded adverse event data revealed that just nine adverse events of any grade were observed in subjects or patients on IKT-148009, and at least four of these adverse events could not be attributed to IKT-148009. The remaining five adverse events were of Grade 1 with no clinical significance. FDA review of the Phase 1/1b data and the protocol for the Phase 2a three-month dosing study resulted in the FDA agreeing with our view that it was appropriate for the Phase 2a study to begin, prompting us to close the Phase 1b study after two dosing cohorts. The Phase 2a '201' study began May 23, 2022 with the opening of the first site; we have opened 16 of 34 selected sites as of November 1, 2022 and 11 patients have randomized into the trial as of November 1, 2022. 120 treatment naïve patients are planned to be enrolled in this study which will dose patients with one of three planned doses of IKT-148009 or placebo once daily for three months. In addition to primary endpoints of safety/tolerability/pharmacokinetics, a hierarchy of 15 secondary endpoints measuring drug impact on motor and non-motor features of Parkinson's disease in the brain or GI tract will be evaluated with descriptive statistics. In November 2022, following review of the IND application to expand the use of IKT-148009 for the Parkinson's-related disorder Multiple System Atrophy, the FDA placed studies of IKT-148009 in Parkinson's and MSA on clinical hold. There have been no serious adverse events in the 201 trial and only two adverse events have been recorded, both graded mild and only one possibly related to the study drug. We are awaiting a detailed description of the basis for the clinical hold from the FDA and plan to work cooperatively with the FDA on resolving their concerns. Once we resolve the basis of the clinical hold for the IKT-148009 programs, and if we are able to have the clinical hold lifted, the 201 trial will have to enroll all 120 patients planned for the study.

In July 2022, we filed our IND with the FDA in preparation to initiate clinical development of IKT-001Pro, our prodrug of imatinib mesylate to treat Stable-phase Chronic Myelogenous Leukemia (SP-CML). IKT-001Pro will be evaluated in a two-part dose finding/dose equivalence study in up to 56 healthy volunteers. The study is designed to evaluate the steady-state pharmacokinetics of IKT-001Pro and determine the dose of IKT-001Pro equivalent to 400 mg imatinib mesylate, the standard-of-care dose for SP-CML. Following clearance of the IND by the FDA on August 26, 2022, the two-part study, now known as the '501' study, was initiated with first patient dosing anticipated by the beginning of December, completion of the first cohort anticipated by year end 2022 and completion of the pharmacokinetic analysis anticipated in early first quarter 2023. Following completion of both parts of this study and assuming the equivalent dose of IKT-001Pro relative to 400 mg imatinib mesylate is established, we will confer with the FDA to begin the NDA process following the proposed approval path for IKT-001Pro under the 505(b)(2) statute. We will simultaneously pursue a superiority study comparing the selected doses of IKT-001Pro to standard-of-care 400 mg imatinib mesylate in SP-CML patients using a novel two-period wait list crossover switching study.

Our programs utilize small molecule, oral protein kinase inhibitors to treat neurodegenerative diseases and cancer. In PD, we have shown in animal models of progressive disease that our lead clinical candidate, IKT-148009, is a brain penetrant Abelson tyrosine kinase, or c-Abl inhibitor, that halts disease progression and reverses functional loss in the brain and reverses neurological dysfunction in the GI tract in animal models of human disease. We have not yet observed reversal of functional loss in humans with IKT-148009. The ability to halt progression and restore function was shown in animal models of progressive disease that mimic the rate of disease progression and the extent of functional loss in the brain and/or the GI tract as found in patients with PD. We believe our therapeutic approach would be disease-modifying. Our understanding of how and why PD progresses has led us to believe that functional loss in Parkinson's patients may be at least partially reversed although this has not been shown clinically. Based on the measurements in animal models, it is possible that patients treated with IKT-148009 may have their disease progression slowed or halted, we may see a progressive reduction in the need for symptomatic or supportive therapy and/or we may ultimately eliminate the need for symptomatic therapy. However, as of the date of this Report, it is unknown whether any of the outcomes seen in the animal models will occur in patients following treatment with IKT-148009.

Impact of the ongoing military conflict between Russia and Ukraine

In late February 2022, Russia invaded Ukraine, significantly amplifying already existing geopolitical tensions among Russia and other countries in the region and in the west, including the U.S. Russia's invasion, the responses of countries and political bodies to Russia's actions, the larger overarching tensions, and Ukraine's military response and the potential for wider conflict have resulted in financial market volatility and capital markets disruption and inflation, potentially increasing in magnitude, and could have severe

adverse effects on regional and global economic markets and international relations. The extent and duration of the military action, sanctions and resulting market disruptions are impossible to predict, but could be substantial.

Following Russia's actions, various countries, including the U.S., Canada and the United Kingdom, as well as the European Union, issued broad-ranging economic sanctions against Russia. Such sanctions included, among other things, a prohibition on doing business with certain Russian companies, officials and oligarchs; a commitment by certain countries and the European Union to remove selected Russian banks from the Society for Worldwide Interbank Financial Telecommunications (SWIFT) electronic banking network that connects banks globally; a ban on Russian oil and gas imports to the U.S.; and restrictive measures to prevent the Russian Central Bank from undermining the impact of the sanctions. The current sanctions (and potential further sanctions in response to continued Russian military activity) and other actions may have adverse effects on regional and global economic markets and lead to instability and lack of liquidity in capital markets, potentially making it more difficult for us to obtain additional funds and increasing the volatility of our stock price. Any of the abovementioned factors could affect our business, prospects, financial condition, and operating results.

We are also monitoring other macro-economic and geopolitical developments such as inflation and cybersecurity risks so that we can be prepared to react to new developments as they arise.

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 INDs and NDAs with the FDA, including our ability to have the FDA lift its clinical hold on our IKT-148009 programs;
- our ability to conduct and continue trials;
- our ability to commence future 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 COVID-19;
- 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.

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, 2022 and 2021

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

	For the Three Months Ended September 30,		Change	
	2022	2021	(\$)	(%)
	(unaudited)			
Grant revenue	\$ 7,291	\$ 328,459	\$ (321,168)	(97.8)
Research and development	(2,981,653)	(3,154,553)	172,900	(5.5)
Selling, general and administrative	(1,538,737)	(1,644,946)	106,209	(6.5)
Loss from operations	(4,513,099)	(4,471,040)	(42,059)	(0.9)
Interest income	18,536	—	18,536	
Interest expense	—	157	157	100.0
Net loss	<u>\$ (4,494,563)</u>	<u>\$ (4,471,197)</u>	<u>\$ (23,366)</u>	(0.5)

Grant Revenue

Grant revenue for the three months ended September 30, 2022, decreased by \$321,168 or (97.8)% to \$7,291 from \$328,459 in the prior year comparable period. During 2022, the Company's focus was shifted toward advancing its PD clinical trials which did not result in significant grant revenue. The Company is utilizing its increased working capital and personnel resources in 2022 to carry on its increasing PD clinical trial activity in addition to nominal grant research activity.

Research and Development

Research and development expenses decreased by \$172,900 or (5.5)% to \$2,981,653 from \$3,154,553 in the prior year comparable period. The \$0.17 million decrease in research and development expenses for the third quarter 2022 was due to a \$0.77 million decrease in stock compensation partially offset by a net increase of \$0.60 million of all other normal R&D expenses expenditures as we continue to focus on and progress in our PD clinical trial activities.

Selling, General and Administrative

Selling, general and administrative expenses decreased by \$106,209 or (6.5)% to \$1,538,737 from \$1,644,946 in the prior year comparable period. The decrease was primarily driven by a \$0.36 million decrease in stock compensation expense partially offset by increases of \$0.13 million and \$0.08 million of legal fees and compensation and related costs, respectively, and a \$0.04 million net increase in all other normal selling, general and administrative expenses.

Interest Income

Interest income increased by \$18,536 from \$0 in the prior comparable period. The increase was driven by interest earned on U.S. Treasuries and money market instruments commencing in July 2022. In the prior comparable period the Company held cash only in non-interest bearing accounts.

Interest Expense

Interest expense decreased by \$157 or 100% to \$0 from \$157 in the prior year comparable period. The decrease was driven by the full settlement of the CEO Note on January 3, 2022. No additional debt has been incurred since settlement of the CEO Note.

Comparison of the Nine Months Ended September 30, 2022 and 2021

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

	For the Nine Months Ended September 30,		(\$)	Change	
	2022	(unaudited) 2021			(%)
Grant revenue	\$ 59,874	\$ 3,098,661	\$ (3,038,787)	(98.1)	
Research and development	(8,980,827)	(7,968,846)	(1,011,981)	12.7	
Selling, general and administrative	(4,872,681)	(4,854,494)	(18,187)	0.4	
Loss from operations	(13,793,634)	(9,724,679)	(4,068,955)	41.8	
Interest income	18,536	—	18,536		
Interest expense	5	19,765	19,760	100.0	
Net loss	<u>\$ (13,775,103)</u>	<u>\$ (9,744,444)</u>	<u>\$ (4,030,659)</u>	41.4	

Grant Revenue

Grant revenue for the nine months ended September 30, 2022 decreased by \$3,038,787 or (98.1)% to \$59,874 from \$3,098,661 in the prior year comparable period. During 2022, the Company's focus was shifted toward advancing its PD clinical trials which did not result in significant grant revenue. The Company is utilizing its increased working capital and personnel resources in 2022 to carry on its increasing PD clinical trial activity in addition to nominal grant research activity.

Research and Development

Research and development expenses increased by \$1,011,981 or 12.7% to \$8,980,827 from \$7,968,846 in the prior year comparable period. The \$1.01 million increase was driven by a \$0.49 million decrease in non-cash stock compensation expenses offset by a \$0.48 million increase in compensation and related costs, a \$0.90 million increase in external R&D services and consultants, a \$0.08 million increase in legal and a net increase of \$0.04 million in all other normal R&D expensed.

Selling, General and Administrative

Selling, general and administrative expenses increased by \$18,187 or 0.4% to \$4,872,681 from \$4,854,494 in the prior year comparable period. Although the overall net change was only \$0.18 million, the major drivers were a \$1.07 million decrease in non-cash stock compensation expense for the nine months ended September 30, 2022 compared to the nine months ended September 30, 2021. The stock compensation decrease was offset by increased compensation and related costs of \$0.38 million, increased legal fees of \$0.35 million, increased compliance, regulatory and consultants of \$0.30 million and a net increase all other normal selling, general and administrative expenses of \$0.02 million.

Interest Income

Interest income increased by \$18,536 from \$0 in the prior comparable period. The increase was driven by interest earned on U.S. Treasuries and money market instruments commencing in July 2022. In the prior comparable period the Company held cash only in non-interest bearing accounts.

Interest Expense

Interest expense decreased by \$19,760 or 100% to \$5 from \$19,765 in the prior year comparable period. The decrease was driven by the full settlement of the CEO Note on January 3, 2022. No additional debt has been incurred since settlement of the CEO Note.

Liquidity and Capital Resources

Sources of Liquidity

From our inception up until our December 2020 Initial Public Offering, we funded our operations primarily through private, state and federal contracts and grants. From our inception through September 30, 2022, we generated aggregate cash proceeds of approximately \$23.5 million from private, state and federal contracts and grants. In June 2021 and December 2020, the Company raised approximately \$41.1 million and \$14.6 million in working capital from its underwritten public offering (the "June 2021 Offering") and its IPO, respectively.

We are able to sell securities on a shelf registration statement pursuant to the Equity Distribution Agreement with Piper Sandler & Co. Under current Securities and Exchange Commission regulations, because our public float was less than \$75 million at the relevant measurement period pursuant to General Instruction I.B.6. to Form S-3, the amount we can raise through primary public offerings of securities in any subsequent 12-month period under our shelf registration statement is limited to an aggregate of one-third of our public float until such time, if any, as our public float is \$75 million or more.

Our ability to issue securities is subject to market conditions.

No securities have been sold under the Equity Distribution Agreement during the nine months ended September 30, 2022.

At September 30, 2022, the Company had working capital of \$24,773,396, an accumulated deficit of \$43,592,790, cash of \$5,781,918, and accounts payable, accrued expenses and other current liabilities of \$3,070,949. The Company had active grants in the amount of \$385,888, of which \$300,386 remained available in accounts held by the U.S. Treasury as of November 1, 2022.

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. Moreover, following the completion of the IPO, we incurred additional costs associated with operating as a public company. We anticipate that we will need substantial additional funding in connection with our continuing operations beyond February 2024.

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 \$43,592,790 at September 30, 2022. 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.

The Company had working capital of \$24,773,396 at September 30, 2022 and active grants in the amount of \$385,888, of which \$300,386 remained available in accounts held by the U.S. Treasury as of November 1, 2022. The Company estimates that its working capital at November 14, 2022 is sufficient to fund its normal operations through February 2024. However, until the Company receives and evaluates the official clinical hold letter from the FDA, it is unable to fully evaluate the effect of the clinical hold on the Company's liquidity. For example, if or when the clinical hold is lifted by the FDA, it is likely that the Company will have to recommence its IKT-148009 201 clinical trial for PD. In such event, the costs of completion of such clinical trial will be greater than originally anticipated.

The accompanying 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 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.

The expected use of the net proceeds from our June 2021 Offering and IPO represents our intentions based upon our current plans and business conditions. 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;
- our ability to successfully lift the current FDA clinical hold on our IKT-148009 programs;
- 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, or our supply chain due to the COVID-19 pandemic;
- 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,	
	2022	2021
Net cash used in operating activities	\$ (13,794,729)	\$ (10,201,234)
Net cash used in investing activities	(20,968,717)	—
Net cash (used in) provided by financing activities	(204,769)	41,093,671
Net (decrease) increase in cash	<u>\$ (34,968,215)</u>	<u>\$ 30,892,437</u>

Net Cash Flows Used in Operating Activities

Net cash flows used in operating activities for the nine months ended September 30, 2022, totaled \$13,794,729, and consisted primarily of a net loss of \$13,775,103 adjusted for non-cash stock compensation of \$357,784, non-cash consulting fees of \$67,000, a decrease of \$825,419 in prepaid research and development, an increase in prepaid expenses and other assets of \$996,801, a decrease in accrued expenses and other current liabilities of \$449,718, a decrease in accounts payable of \$308,555, and an increase in grants receivable of \$96,299.

Net cash flows used in operating activities for the nine months ended September 30, 2021, totaled \$10,201,234, and consisted primarily of a net loss of \$9,744,444 adjusted for non-cash stock compensation of \$1,266,026, non-cash warrant expense of \$658,945, non-cash consulting fees of \$60,391, non-cash PPP loan forgiveness of \$27,550, a decrease in grants receivable of \$217,482, a decrease in prepaid expenses of \$486,551, a decrease of \$509,975 in prepaid research and development, a decrease in accounts payable of \$1,166,879, an increase in accrued expenses of \$1,272,076, and a decrease in deferred revenue of \$2,325,741.

Cash Used in Investing Activities

Net cash flows used in investing activities for the nine months ended September 30, 2022, totaled \$20,968,717, of which \$243,255 was used for the purchase of equipment and \$20,725,462 was used for the purchase of marketable securities investments.

Cash Provided by Financing Activities

Net cash flows used in financing activities for the nine months ended September 30, 2022, totaled \$204,769, which primarily was from the full settlement of the CEO Note on January 3, 2022 offset by proceeds from a stock option exercise.

Net cash flows provided by financing activities for the nine months ended September 30, 2021, totaled \$41,093,671, which primarily consisted of cash flows from capital raises of \$41,149,608.

Off-Balance Sheet Arrangements

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

Contractual Obligations and Commitments

In June 2018, the Company entered into a one-year, noncancelable operating lease for space in Boston, Massachusetts. The total lease obligation was \$54,000, payable in 12 equal monthly installments commencing August 1, 2018. On April 18, 2022, the Company entered into an operating lease agreement through July 31, 2025 for its office space in Lexington, Massachusetts to replace the office space in Boston, Massachusetts. The Company vacated the Boston office during the third quarter of 2022 without further contractual obligation. The Lexington space is expected to be ready for use and occupancy during the third quarter 2022. 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 \$444,366, consisting of minimum annual rental obligations of \$33,469 for fiscal year 2022, \$145,836 for fiscal year 2023, \$150,095 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 financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States, or US GAAP. The preparation of these 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 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 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 statements of operations. 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, 2022.

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) under the Exchange Act) during the three months ended September 30, 2022, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

None.

Item 1A. Risk Factors.

Not applicable as we are a smaller reporting company.

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	Form	Incorporated by Reference to SEC Filing		
			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	Amended and Restated Bylaws of Inhibikase Therapeutics, Inc., as most recently amended and restated effective Wednesday, December 28, 2020.	8-K	3.2	001-39676	12/29/2020
10.1#	Form of Director Offer Letter	8-K	10.1#	001-39676	9/1/2022
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, 2022

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

Date: November 14, 2022

By: /s/ JOSEPH FRATTAROLI
Joseph Frattaroli
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

**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, 2022

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

I, Joseph Frattaroli, 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/ Joseph Frattaroli

Joseph Frattaroli
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

Date: November 14, 2022

**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, 2022 (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, 2022

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

A signed original of this written statement required by Section 906, or other document authenticating, acknowledging, or otherwise adopting the signature that appears in typed form within the electronic version of this written statement required by Section 906, has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

**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, 2022 (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, 2022

By: /s/ Joseph Frattaroli
Joseph Frattaroli
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

A signed original of this written statement required by Section 906, or other document authenticating, acknowledging, or otherwise adopting the signature that appears in typed form within the electronic version of this written statement required by Section 906, has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.
