

**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, 2021

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 10, 2021, the registrant had 25,155,198 shares of common stock, \$0.001 par value per share, outstanding.

Table of Contents

	Page
PART I.	<u>FINANCIAL INFORMATION</u>
Item 1.	<u>Condensed Financial Statements (Unaudited)</u>
	1
	<u>Condensed Balance Sheets as of September 30, 2021 (Unaudited) and December 31, 2020</u>
	1
	<u>Condensed Statements of Operations for the Three and Nine Months Ended September 30, 2021 and 2020 (Unaudited)</u>
	2
	<u>Condensed Statements of Stockholders' Equity (Deficit) for the Three and Nine Months Ended September 30, 2021 and 2020 (Unaudited)</u>
	3
	<u>Condensed Statements of Cash Flows for the Nine Months Ended September 30, 2021 and 2020 (Unaudited)</u>
	4
	<u>Notes to Unaudited Condensed Financial Statements</u>
	5
Item 2.	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>
	12
Item 3.	<u>Quantitative and Qualitative Disclosures About Market Risk</u>
	20
Item 4.	<u>Controls and Procedures</u>
	20
PART II.	<u>OTHER INFORMATION</u>
	21
Item 1.	<u>Legal Proceedings</u>
	21
Item 1A.	<u>Risk Factors</u>
	21
Item 2.	<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>
	21
Item 3.	<u>Defaults Upon Senior Securities</u>
	21
Item 4.	<u>Mine Safety Disclosures</u>
	21
Item 5.	<u>Other Information</u>
	21
Item 6.	<u>Exhibits</u>
	22
<u>Signatures</u>	23

PART I—FINANCIAL INFORMATION

Item 1. Condensed Financial Statements (Unaudited).

Inhibikase Therapeutics, Inc.
Condensed Balance Sheets

	September 30, 2021 (unaudited)	December 31, 2020 (Note 3)
Assets		
Current assets:		
Cash	\$ 44,845,950	\$ 13,953,513
Grants receivable	217,482	—
Prepaid research and development	264,381	774,356
Prepaid expenses and other current assets	541,388	54,837
Total assets	<u>\$ 45,869,201</u>	<u>\$ 14,782,706</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 553,801	\$ 1,720,680
Accrued expenses and other current liabilities	1,905,010	632,934
Deferred revenue	—	2,325,741
Notes payable	248,911	42,534
Total	2,707,722	4,721,889
Notes payable, net of current portion	—	276,461
Total liabilities	2,707,722	4,998,350
Commitments and contingencies (see Note 11)		
Stockholders' equity:		
Preferred stock, \$0.001 par value; 10,000,000 shares authorized at September 30, 2021 and December 31, 2020; 0 shares issued and outstanding at September 30, 2021 and December 31, 2020	—	—
Common stock, \$0.001 par value; 100,000,000 and 30,000,000 shares authorized; 25,155,198 and 10,050,849 shares issued and outstanding at September 30, 2021 and December 31, 2020, respectively.	25,155	10,051
Additional paid-in capital	67,912,392	24,805,929
Accumulated deficit	(24,776,068)	(15,031,624)
Total	43,161,479	9,784,356
Total liabilities and stockholders' equity	<u>\$ 45,869,201</u>	<u>\$ 14,782,706</u>

See accompanying notes to condensed financial statements.

Inhibikase Therapeutics, Inc.
Condensed Statements of Operations
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Revenue:				
Grant revenue	\$ 328,459	\$ 37,680	\$ 3,098,661	\$ 528,052
Total revenue	328,459	37,680	3,098,661	528,052
Costs and expenses:				
Research and development	3,154,553	120,569	7,968,846	666,858
Selling, general and administrative	1,644,946	580,820	4,854,494	1,478,839
Total costs and expenses	4,799,499	701,389	12,823,340	2,145,697
Loss from operations	(4,471,040)	(663,709)	(9,724,679)	(1,617,645)
Interest expense	(157)	(6,890)	(19,765)	(22,263)
Net loss	<u>\$ (4,471,197)</u>	<u>\$ (670,599)</u>	<u>\$ (9,744,444)</u>	<u>\$ (1,639,908)</u>
Net loss per share – basic and diluted	<u>\$ (0.18)</u>	<u>\$ (0.08)</u>	<u>\$ (0.61)</u>	<u>\$ (0.20)</u>
Weighted-average number of common shares – basic and diluted	<u>25,143,559</u>	<u>8,198,754</u>	<u>15,868,421</u>	<u>8,187,517</u>

See accompanying notes to condensed financial statements.

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

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
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	25,133,345	\$ 25,134	\$ 67,334,089	\$ (20,304,871)	\$ 47,054,352
Stock-based compensation expense	—	—	352,419	—	352,419
Warrant expense	—	—	181,762	—	181,762
Issuance of common stock, stock options exercised	21,853	21	44,122	—	44,143
Net loss	—	—	—	(4,471,197)	(4,471,197)
Balance at September 30, 2021	25,155,198	\$ 25,155	\$ 67,912,392	\$ (24,776,068)	\$ 43,161,479

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount			
Balance at December 31, 2019	8,180,937	\$ 8,181	\$ 7,685,533	\$ (12,183,730)	\$ (4,490,016)
Stock-based compensation expense	—	—	139,758	—	139,758
Warrant expense	—	—	190,993	—	190,993
Issuance of common stock	874	1	4,870	—	4,871
Net loss	—	—	—	(547,440)	(547,440)
Balance at March 31, 2020	8,181,811	\$ 8,182	\$ 8,021,154	\$ (12,731,170)	\$ (4,701,834)
Stock-based compensation expense	—	—	139,759	—	139,759
Warrant expense	—	—	89,515	—	89,515
Conversion of notes	11,594	11	63,789	—	63,800
Net loss	—	—	—	(421,869)	(421,869)
Balance at June 30, 2020	8,193,405	\$ 8,193	\$ 8,314,217	\$ (13,153,039)	\$ (4,830,629)
Stock-based compensation expense	—	—	139,758	—	139,758
Warrant expense	—	—	236,415	—	236,415
Issuance of common stock, cashless warrant exercise	13,301	14	(15)	—	(1)
Net loss	—	—	—	(670,599)	(670,599)
Balance at September 30, 2020	8,206,706	\$ 8,207	\$ 8,690,375	\$ (13,823,638)	\$ (5,125,056)

See accompanying notes to condensed financial statements.

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

	Nine Months Ended September 30,	
	2021	2020
Operating activities		
Net loss	\$ (9,744,444)	\$ (1,639,908)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	1,266,026	419,275
Non-cash consulting fees	60,391	112,500
Non-cash PPP loan forgiveness	(27,550)	—
Warrant expense	658,945	516,923
Changes in operating assets and liabilities:		
Grants receivable	(217,482)	—
Prepaid expenses and other assets	(486,551)	3,218
Prepaid research and development	509,975	—
Accounts payable	(1,166,879)	1,046,755
Accrued expenses and other current liabilities	1,272,076	(1,171,508)
Deferred revenue	(2,325,741)	529,918
Net cash used in operating activities	(10,201,234)	(182,827)
Financing activities		
Proceeds from notes payable	—	272,800
Proceeds from issuance of common stock	41,135,357	4,870
Deferred initial public offering costs	—	(97,132)
Issuance of common stock from exercise of stock options	78,500	—
Payment of employee taxes in connection with stock option exercise	(77,652)	—
Repayments of note payable	(42,534)	—
Net cash provided by financing activities	41,093,671	180,538
Net increase (decrease) in cash	30,892,437	(2,289)
Cash at beginning of period	13,953,513	18,457
Cash at end of period	<u>\$ 44,845,950</u>	<u>\$ 16,168</u>
Supplemental disclosures of cash flow information		
Cash paid for interest	<u>\$ 19,608</u>	<u>\$ 4,520</u>
Non-cash financing activities		
Notes payable settled with new notes payable	<u>\$ —</u>	<u>\$ 42,534</u>
Notes payable settled with common stock	<u>\$ —</u>	<u>\$ 63,800</u>
PPP loan forgiveness	<u>\$ 27,550</u>	<u>\$ —</u>
Accrued deferred initial public offering costs	<u>\$ —</u>	<u>\$ 1,334,331</u>

See accompanying notes to condensed financial statements.

Inhibikase Therapeutics, Inc.
Notes to Unaudited Condensed 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 that arise inside and outside of the brain. 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 and its manifestation in the gastrointestinal tract, or GI. Results to date of our ongoing Phase 1 Single and Multiple Ascending Dose escalation study ("SAD" and "MAD", respectively) in older and elderly healthy volunteers have revealed important insights into the safety, tolerability and pharmacokinetics of IKT-148009 in human subjects. Outcomes of this study led to an acceleration of the clinical development program. In July 2021, the U.S. Food and Drug Administration ("FDA") agreed with the Company's plan to initiate its Phase 1b study in Parkinson's patients which commenced dosing October 19, 2021. Clinical development of IKT-148009 for the GI complications in PD patients will cross-reference the Phase 1 study of IKT-148009 for the treatment of PD. Clinical development of the Company's lead oncology asset, IKT-001Pro, is anticipated to begin shortly after submission of Company's Investigational New Drug application for IKT-001Pro; submission of the IND is anticipated to occur in the first quarter of 2022. The Company's pursuit of the orphan indication Multiple System Atrophy is ongoing with regulators in the U.S. and Europe.

2. Liquidity and Going Concern

The Company has recognized recurring losses. At September 30, 2021, the Company had working capital of \$43,161,479, an accumulated deficit of \$24,776,068, cash of \$44,845,950, accounts payable and accrued expenses of \$2,458,811 and notes payable of \$248,911. The Company had active grants in the amount of \$1,932,618, of which \$519,813 remained available in accounts held by the U.S. Treasury as of October 29, 2021.

The future success of the Company is dependent on its ability to successfully obtain additional working capital, obtain regulatory approval for and successfully launch and commercialize its product candidates and to ultimately attain profitable operations. Historically, the Company has 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, 2021 is sufficient to fund its normal operations into the first quarter of 2023.

The accompanying condensed 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 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 financial statements were prepared by the Company pursuant to the rules and regulations of the Securities and Exchange Commission (“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, 2020 balance sheet was derived from December 31, 2020 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, 2021. The condensed unaudited 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, 2020 included in the Company’s Annual Report filed on SEC Form 10-K.

These condensed financial statements have been prepared on the assumption that the Company will be able to realize its assets and discharge its liabilities in the normal course of business. The condensed financial statements do not include any adjustments relating to recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might be necessary should the Company be unable to continue as a going concern.

On August 21, 2020, the Company filed a Certificate of Amendment of its Certificate of Incorporation with the Secretary of State of the State of Delaware that effected a one-for-1.14396 (1:1.14396) reverse stock split of its common stock, par value \$.001 per share, effective August 24, 2020. All warrant, option, share, and per share information in the Company’s financial statements gives retroactive effect to the one-for-1.14396 reverse stock split that was effected on August 24, 2020.

The condensed financial statements have been prepared in conformity with US GAAP. 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 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 months ended September 30, 2021 and 2020, 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 condensed 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.

4. Supplemental Balance Sheet Information

Accrued expenses and other current liabilities consist of the following:

	September 30, 2021	December 31, 2020
Accrued consulting	\$ 256,342	\$ 115,405
Accrued legal and professional fees	—	383,286
Accrued research and development	1,483,479	83,491
Accrued interest	811	1,673
Accrued bonuses	152,860	—
Accrued other	11,518	49,079
Total accrued expenses and other current liabilities	<u>\$ 1,905,010</u>	<u>\$ 632,934</u>

5. Notes Payable

Notes payable outstanding were \$248,911 and \$318,995 at September 30, 2021 and December 31, 2020, respectively.

	September 30, 2021	December 31, 2020
Fifth Restated Note	\$ —	\$ 42,534
PPP Note	—	27,550
CEO Restated Note	248,911	248,911
Total notes payable	<u>\$ 248,911</u>	<u>\$ 318,995</u>

Future principal payments on the notes payable as of September 30, 2021, are as follows:

Year ending December 31,	
2021	\$ —
2022	248,911
2023	—
2024	—
2025	—
Total notes payable	<u>\$ 248,911</u>

Revolving Demand Promissory Note

During 2019 and 2020, the Company entered into a series of promissory notes that were renegotiated and partially settled over 2019 and 2020.

On January 1, 2020, the Company issued a note (the “2020 Note”) in the face amount of \$103,586 bearing 5.25% APR simple interest as settlement in full on the 2019 Note principal of \$98,419 plus accrued interest of \$5,167 that matured on January 1, 2020. The 2020 Note was scheduled to mature on January 1, 2021. Upon occurrence of certain conditions including the sale of a division of the Company or upon the date on which the Company closes on certain financings, the due date for some or all of the unpaid principal and accrued and unpaid interest may be accelerated. The Company assessed the terms and features of the 2020 Note and determined that none of the terms and features represented embedded derivatives that require bifurcation.

On June 30, 2020, the holder of the 2020 Note and the Company entered into an agreement to settle the 2020 Note early. As full consideration and settlement of the 2020 Note’s June 30, 2020 principal balance plus accrued and unpaid interest in the amount of \$106,334, the Company issued a new promissory note to the holder in the amount of \$42,534 (the “Fifth Restated Note”) with substantially similar terms as the 2020 Note. In addition, the holder subscribed for the purchase of 11,594 unregistered shares of the Company’s common stock at a subscription price of \$63,800, or \$5.50 per share. The issuance of shares under the subscription

agreement and the issuance of the Fifth Restated Note satisfied the payoff of the 2020 Note without premium or discount. The balance of the Fifth Restated Note was \$42,534 on December 31, 2020 and is included in Notes payable.

The Fifth Restated Note was scheduled to mature on the earlier of a significant transaction, including an initial public offering, sale of substantially all assets or change of control, or January 1, 2021. The Company consummated its IPO on December 28, 2020 and the principal balance of the Fifth Restated Note plus accrued and unpaid interest was settled in full in cash on January 1, 2021.

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 occurs and is continuing, the Company agrees 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 extends 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, is 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 are the same, in all material respects, to the CEO Note. The Company and its CEO have agreed that the CEO Restated Note will be repaid by the end of first half of 2022. The principal balance of the CEO Note was \$248,911 at September 30, 2021 and at December 31, 2020 and is included on the condensed balance sheets in Notes payable at September 30, 2021 and Notes payable, net of current portion at December 31, 2020.

The Paycheck Protection Program Loan (the "PPP Loan")

On May 4, 2020 the Company received \$27,550 in loan proceeds as part of the Federal Coronavirus Aid, Relief and Economic Security Act Paycheck Protection Program (the "PPP Act" or "PPP") with a 1% annual interest rate. Some or all of this loan qualified for forgiveness if the Company expended not less than 60% of the loan proceeds on qualified payroll costs. During the nine months ended September 30, 2021, it was determined by the lender and by the Small Business Administration that the Company met the contractual conditions for forgiveness of the entire PPP Loan plus accrued interest and it was forgiven. The \$27,550 principal balance of the PPP Loan at December 31, 2020 is included on the condensed balance sheet in Notes payable, net of current portion.

6. Stockholders' Equity (Deficit)

Each share of common stock is entitled to one vote. The holders of common stock are also entitled to receive dividends whenever funds are legally available and when declared by the board of directors, subject to the prior rights of holders of all classes of stock outstanding. A total of 5,191,957 and 4,318,357 shares of common stock were reserved for issuance upon the exercise of outstanding stock options and warrants as of September 30, 2021 and December 31, 2020, respectively.

Reverse Stock Split

On August 20, 2020, the board of directors adopted resolutions proposing that each 1.14396 shares of the Company's issued and outstanding common stock, par value \$0.001 per share, be automatically converted into one fully paid and non-assessable share of common stock, par value \$0.001 (the "Reverse Stock Split") with cash in lieu of fractional shares. On August 21, 2020, shareholders representing a majority of the issued and outstanding common stock approved the Reverse Stock Split. On August 21, 2020, the Company filed with the Delaware Secretary of State its Certificate of Amendment to its Certificate of Incorporation, effective as of August 24, 2020.

Share Issuances

In January 2020, an accredited investor subscribed for, and the Company issued, 874 shares of its stock in a private placement transaction at a per share price of \$5.57. Net proceeds were approximately \$4,870. Issuance costs were not material. No additional rights or options were granted to this accredited investor in connection with this issuance.

During the nine months ended September 30, 2021, an accredited investor subscribed for, and the Company issued, 9,000 shares of its stock in exchange for consulting services. The fair value of the 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 is a component of selling, general and administrative costs for the nine months ended September 30, 2021.

During the nine months ended September 30, 2020 the Company issued 95,349 shares of its stock in connection with the exercise of non-qualified stock options.

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. The net proceeds are and will be used as working capital by the Company.

7. Stock-Based Compensation

2020 Equity Incentive Plan

The Company's 2020 Equity Incentive Plan (the "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, 2021, the Company granted 68,628 options 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.

In May 2021, the Company issued 73,496 shares of its common stock in connection with the exercise of non-qualified stock options with a strike price of \$0.38 per share. All such securities were issued without registration under the Securities Act of 1933, as amended, in reliance upon the exemption afforded by Section 4(a)(2) of that Act.

In June 2021, the Company issued 21,854 shares of its common stock in connection with the exercise of non-qualified stock options with a strike price of \$2.02 per share. All such securities were issued without registration under the Securities Act of 1933, as amended, in reliance upon the exemption afforded by Section 4(a)(2) of that Act.

In August 2021, 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. All such securities were issued without registration under the Securities Act of 1933, as amended, in reliance upon the exemption afforded by Section 4(a)(2) of that Act.

No options were granted during the nine months ended September 30, 2020.

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,	
	2021	2020
Research and development	\$ 592,966	\$ 195,061
Selling, general and administrative	673,060	224,214
Total stock-based compensation expense	<u>\$ 1,266,026</u>	<u>\$ 419,275</u>

8. Warrants

Warrants Issued

On March 31, 2020, the Company issued a warrant to purchase up to 26,225 shares of its stock to one of its consultants in exchange for services. The warrant contains a strike price of \$5.67 per share and has a seven-year contractual term. The warrant is

classified within stockholders' equity at its fair value and was treated as a standalone instrument. The fair value of the warrant was determined to be \$101,478 utilizing the Black-Scholes-Merton option-pricing model at the time of issuance and is included in selling, general and administrative expenses for the nine months ended September 30, 2020. The Company recognized \$658,945 in warrant expense for the nine months ended September 30, 2021, included in selling, general and administration expense.

In connection with the June 2021 Offering the Company issued and sold to its underwriters a warrant to purchase up to 750,000 shares of its common stock for an aggregate purchase price of \$100 pursuant to its written agreement with the underwriters. This warrant is exercisable beginning June 15, 2022 at an initial exercise price of \$3.75 per share of common stock.

Warrants Exercised

No warrants were exercised for the nine months ended September 30, 2021 and 2020.

9. 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,	
	2021	2020
Numerator:		
Net loss	\$ (9,744,444)	\$ (1,639,908)
Denominator:		
Weighted-average number of common shares outstanding – basic and diluted	15,868,421	8,187,517
Net loss per share applicable to common stockholders – basic and diluted	\$ (0.61)	\$ (0.20)

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,	
	2021	2020
Options to purchase shares of stock	3,630,044	3,369,144
Warrants to purchase shares of stock	1,561,913	650,948
Total	5,191,957	4,020,092

10. Income Taxes

During the nine months ended September 30, 2021 and 2020, 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.

11. Commitments and Contingencies

Impact of the COVID-19 Pandemic on Our Operations

The novel coronavirus SARS-Cov2, or COVID-19, pandemic is causing 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 conducting its clinical trials.

Although the Company did not experience a material impact on its operations during the nine months ended September 30, 2021 and 2020, 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.

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

Forward-Looking Statements

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 Quarterly Report on Form 10-Q ("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. These forward-looking statements are based on our current expectations, estimates, approximations and projections about our industry and business, management's beliefs, and certain assumptions made by us, all of which are subject to change. Forward-looking statements can often be identified by words such as "anticipates," "expects," "intends," "plans," "predicts," "believes," "seeks," "estimates," "may," "will," "should," "would," "could," "potential," "continue," "ongoing," and similar expressions and variations or negatives of these words. These statements are not guarantees of future performance and are subject to risks, uncertainties and assumptions that are difficult to predict. Therefore, our actual results could differ materially and adversely from those expressed in any forward-looking statements as a result of various factors. These forward-looking statements speak only as of the date of this Report. We undertake no obligation to revise or update publicly any forward-looking statement for any reason, except as otherwise required by law.

Overview

We are a clinical stage pharmaceutical company developing therapeutics for Parkinson's Disease, or "PD", and related disorders that arise inside and outside of the brain. 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 and its manifestation in the gastrointestinal tract, or "GI". Results to date of our ongoing Phase 1 Single and Multiple Ascending Dose escalation study ("SAD" and "MAD", respectively) in older and elderly healthy volunteers have revealed important insights into the metabolism of IKT-148009 in human subjects. We enrolled 56 subjects in the Phase 1 study. Results from the Phase 1 study have shown that IKT-148009 has a half-life of greater than 24 hours and just a 25 mg once daily oral dose in older and elderly healthy subjects in our Phase 1 study reached exposures that are consistent with the exposure to the drug that resulted in therapeutic efficacy in animal models of progressive Parkinson's disease. Following agreements with the Food and Drug Administration or "FDA", we initiated dosing in a Parkinson's patient population as part of the Phase 1 MAD study on October 19, 2021. Clinical development of IKT-148009 for the GI complications in PD patients will cross-reference the Phase 1 Study of IKT-148009 for the treatment of PD. In support of our clinical development program, we have now completed three months of our chronic toxicology program of IKT-148009 in both rats and monkeys and the data was submitted to the FDA in early 4Q21. These toxicology studies have completed three additional months in rats, the statutory requirement, and will complete six additional months in monkeys in mid-4Q21. Completion of these chronic toxicology studies will permit chronic dosing in patients following FDA submission of the data and their review in 1Q22.

We have also advanced our pre-clinical and clinical development program for the Parkinson's-related disease Multiple Systems Atrophy, or "MSA". We received a grant from the National Institute of Neurological Diseases and Stroke, or "NINDS", an Institute of the National Institutes of Health, for \$385,888 to fund animal model studies of IKT-148009 as a therapy for MSA. These animal studies are now underway. At the same time, we are preparing regulatory submissions to the European Medicines Agency, or "EMA", and to the U.S. FDA to enable a Phase 2a safety and tolerability study in MSA patients across up to 19 sites in the European Union, or "EU", and up to 6 sites in the U.S. The proposed clinical Phase 2a study will have primary endpoints in safety and tolerability and exploratory endpoints in MSA efficacy parameters with 3 month daily dosing at two different doses. While we complete the set-up of the Phase 2a study in MSA, we will complete at least one model study to support advancing IKT-148009 into patients by the third-quarter of 2022. Dosing of patients with MSA will depend on a positive outcome in animal model studies; if IKT-148009 is not a successful therapy in MSA model studies, the Phase 2a clinical study will not proceed. In this circumstance, the regulatory effort for IKT-148009 with the EMA will be applied to future studies of Parkinson's Disease efficacy in the EU.

Finally, we have also advanced clinical batch manufacturing and pill formulation for our platform prodrug technology involving IKT-001Pro. The IND for IKT-001Pro has been delayed due to the impurity level in the clinical batch that was slightly higher than the level of this impurity in the toxicology study batch. It is expected that the clinical batch manufacturing will complete in 4Q21 and the IND filed in 1Q22, to include the production of the data package for the final pill formulation.

In the ensuing 12 months, the Company anticipates reporting the full outcomes of its completed Phase 1 study of IKT-148009 in older and elderly healthy subjects, completing the ongoing chronic toxicology studies in rats and monkeys for IKT-148009 to enable chronic drug administration in Parkinson's patients, completing a Phase 1b extension study of IKT-148009 in Parkinson's patients and initiating its Phase 2 efficacy study in Parkinson's patients. Advancement of IKT-148009 into Phase 1b was approved by the FDA July 22, 2021; advancement to proceed with the Phase 2 programs with IKT-148009 is subject to agreement on the protocol to be proposed for these trials in 4Q21. We further anticipate initiating the Phase 2a clinical study in MSA, subject to a successful model study outcome. Finally, we intend to advance IKT-001Pro through IND filing and initiate clinical development, possibly completing clinical development in 2022.

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:

- ① 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;
- ① fees related to our license and collaboration agreements;
- ① personnel related expenses, including salaries, benefits and non-cash stock-based compensation expense; and
- ① 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:

- ① our ability to add and retain key research and development personnel and other key employees;
- ① our ability to successfully file investigational new drug ("IND") and new drug applications ("NDA") with the FDA;
- ① our ability to conduct and continue trials;
- ① our ability to commence future trials;
- ① our ability to establish an appropriate safety profile with IND-enabling toxicology studies;
- ① our ability to successfully develop, obtain regulatory approval for, and then successfully commercialize our product candidates;

- ② our successful enrollment in and completion of our current and future clinical trials;
- ② the costs associated with the development of any additional product candidates we identify in-house or acquire through collaborations;
- ② our ability to discover, develop and utilize biomarkers to demonstrate target engagement, pathway engagement and the impact on disease progression of our molecules;
- ② 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;
- ② the terms and timing of any collaboration, license or other arrangement, including the terms and timing of any milestone payments thereunder;
- ② 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;
- ② our receipt of marketing approvals from applicable regulatory authorities;
- ② the impact of the outbreak of the novel coronavirus disease, COVID-19, pandemic which has had an adverse impact on our business, including our preclinical studies and clinical trials;
- ② our ability to commercialize products, if and when approved, whether alone or in collaboration with others; and
- ② 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 Cambridge, Massachusetts and Atlanta, Georgia not otherwise included in research and development expenses.

We expect to incur 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 any national securities exchange on which our securities are traded, additional insurance expenses, investor relations activities and other administrative and professional services. We also expect to increase our administrative headcount when operating 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, 2021 and 2020

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

	For the Three Months Ended September 30,		Change	
	2021	2020	(\$)	(%)
	(unaudited)			
Grant revenue	\$ 328,459	\$ 37,680	\$ 290,779	771.7
Research and development	(3,154,553)	(120,569)	(3,033,984)	2,516.4
Selling, general and administrative	(1,644,946)	(580,820)	(1,064,126)	183.2
Loss from operations	(4,471,040)	(663,709)	(3,807,331)	(573.6)
Interest expense, net	(157)	(6,890)	6,733	(97.7)
Net loss	<u>\$ (4,471,197)</u>	<u>\$ (670,599)</u>	<u>\$ (3,800,598)</u>	<u>(566.7)</u>

Grant Revenue

Grant revenue for the three months ended September 30, 2021, increased by \$290,779 or 772% to \$328,459 from \$37,680 in the prior year comparable period. The increase was driven by increased grant research activity during 2021 compared to 2020. During 2020, the Company's focus was shifted toward advancing its Phase I clinical trial which did not result in grant revenue. The Company is utilizing its increased working capital and personnel resources in 2021 to carry on its Phase I clinical trial in addition to its grant research activity.

Research and Development

Research and development expenses increased by \$3,033,984 or 2,516% to \$3,154,553 from \$120,569 in the prior year comparable period. The increase was driven by a \$0.3 million increase in grant related research expenditures and a \$2.7 million increase in non-grant related research. The non-grant related research was expended primarily in connection with the Company's Phase I PD clinical trial.

Selling, General and Administrative

Selling, general and administrative expenses increased by \$1,064,126 or 183% to \$1,644,946 from \$580,820 in the prior year comparable period. The increase was primarily the result of increased non-cash stock compensation expense of \$0.1 million, increased director and officer's liability insurance of \$0.4 million related to the Company's IPO in December 2020, increased legal fees, board fees, investor relation and consulting fees of \$0.3 million relating to operating as a public company registrant since December 2020 and a net increase of \$0.3 million for other normal operating expenses.

Interest Expense

Interest expense decreased by \$6,733 or (98)% to \$157 from \$6,890 in the prior year comparable period. The decrease was driven by a significant decrease in outstanding notes payable which were settled upon completion of the December 2020 IPO. The Company entered into a D&O insurance premium financing agreement during January 2021 which was repaid in full from the proceeds of the June 2020 Offering and no D&O financing interest was incurred for the three months ended September 30, 2021.

Comparison of the Nine Months Ended September 30, 2021 and 2020

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

	For the Nine Months Ended September 30,		Change	
	2021 (unaudited)	2020	(\$)	(%)
Grant revenue	\$ 3,098,661	\$ 528,052	\$ 2,570,609	486.8
Research and development	(7,968,846)	(666,858)	(7,301,988)	1,095.0
Selling, general and administrative	(4,854,494)	(1,478,839)	(3,375,655)	228.3
Loss from operations	(9,724,679)	(1,617,645)	(8,107,034)	501.2
Interest expense, net	(19,765)	(22,263)	2,498	(11.2)
Net loss	<u>\$ (9,744,444)</u>	<u>\$ (1,639,908)</u>	<u>\$ (8,104,536)</u>	494.2

Grant Revenue

Grant revenue for the nine months ended September 30, 2021, increased by \$2,570,609 or 487% to \$3,098,661 from \$528,052 in the prior year comparable period. The increase was driven by increased grant research activity during 2021 compared to 2020. During 2020, the Company's focus was shifted toward advancing its Phase I clinical trial which did not result in grant revenue. The Company is utilizing its working capital and personnel resources in 2021 to carry on its Phase I clinical trial in addition to its grant research activity.

Research and Development

Research and development expenses increased by \$7,301,988 or 1,095% to \$7,968,846 from \$666,858 in the prior year comparable period. The increase was driven by a \$2.4 million increase in grant related research expenditures and a \$4.9 million increase in non-grant related research. The non-grant related research and development was expended primarily in connection with the Company's ongoing Phase I PD clinical trial which commenced in 2021.

Selling, General and Administrative

Selling, general and administrative expenses increased by \$3,375,655 or 228% to \$4,854,494 from \$1,478,839 in the prior year comparable period. The increase was primarily the result of increased non-cash stock compensation expense of \$0.6 million, increased director and officer's liability insurance of \$1.1 million related to the Company's initial public offering in December 2020, increased legal fees, board fees, investor relation and consulting fees of \$0.9 million relating to operating as a public company registrant since December 2020, administrative wages of \$0.4 million and a net increase of \$0.4 million for other normal operating expenses.

Interest Expense

Interest expense decreased by \$2,498 or (11)% to \$19,765 from \$22,263 in the prior year comparable period. The net decrease was driven by a significant decrease in outstanding notes payable which were settled upon completion of the December 2020 IPO, partially offset by interest expense incurred during 2021 in connection with D&O insurance premium financing. The D&O insurance premium loan was repaid in full from the proceeds of the June 2021 Offering. In the 2020 comparable period insurance premiums were not significant, prior to the December 2020 IPO, and were not financed.

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, 2021, 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 June 2021 Offering and its IPO, respectively.

At September 30, 2021, the Company had working capital of \$43,161,479, an accumulated deficit of \$24,776,068, cash of \$44,845,950, and accounts payable and accrued expenses of \$2,458,811. The Company had active grants in the amount of \$1,932,618, of which \$519,813 remained available in accounts held by the U.S. Treasury as of October 29, 2021.

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 December 2020 IPO, we are incurring 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 the first quarter of 2023.

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 \$24,776,068 at September 30, 2021. 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 \$43,161,479 at September 30, 2021 and active grants in the amount of \$1,932,618, of which \$519,813 remained available in accounts held by the U.S. Treasury as of October 29, 2021. The Company estimates that its working capital at September 30, 2021 is sufficient to fund its normal operations into the first quarter of 2023.

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 December 2020 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;

- ⌚ 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,	
	2021	2020
Net cash used in operating activities	\$ (10,201,234)	\$ (182,827)
Net cash provided by financing activities	41,093,671	180,538
Net increase (decrease) in cash	<u>\$ 30,892,437</u>	<u>\$ (2,289)</u>

Net Cash Flows Used in Operating Activities

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 of \$509,975 in prepaid research and development, an increase in prepaid expenses and other assets of \$486,551, an increase in accrued expenses and other current liabilities of \$1,272,076, a decrease in accounts payable of \$1,166,879, a decrease in deferred revenue of \$2,325,741 and an increase in grants receivable of \$217,482.

Net cash flows used in operating activities for the nine months ended September 30, 2020, totaled \$182,827, and consisted primarily of a net loss of \$1,639,908 adjusted for non-cash stock compensation of \$419,275, non-cash warrant expense of \$516,923, non-cash consulting fees of \$112,500, a decrease in prepaid expenses of \$3,218, an increase in accounts payable of \$1,046,755, a decrease in accrued expenses of \$1,171,508, and an increase in deferred revenue of \$529,918.

Cash Provided by Financing Activities

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 raise of \$41,149,608.

Net cash flows provided by financing activities for the nine months ended September 30, 2020, totaled \$180,538, which consisted of proceeds of \$272,800 from the issuance of notes payable, \$4,870 from the issuance of common stock partially offset by deferred IPO costs of \$97,132.

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, non-cancelable operating lease for space in Boston, Massachusetts. The total lease obligation was \$54,000, payable in 12 equal monthly installments commencing August 1, 2018. Since the end of the one-year initial term on July 31, 2019, the lease continues on a month-to-month basis.

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 are 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, 2021.

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 nine months ended September 30, 2021, 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.

In August 2021, 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. All such securities were issued without registration under the Securities Act of 1933, as amended, in reliance upon the exemption afforded by Section 4(a)(2) of that Act.

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	Underwriting Agreement dated June 15, 2021 by and between Inhibikase Therapeutics, Inc. and ThinkEquity, a division of Fordham Financial Management, Inc., as representative of the underwriters listed on Schedule 1 thereto.	8-K	1.1	001-39676	6/16/2021
10.2	Form of Representative's Warrant Agreement	8-K	4.2	001-39676	6/16/2021
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.

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 15, 2021

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

Date: November 15, 2021

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)) 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) 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

(c) 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 15, 2021

**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)) 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) 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

(c) 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 15, 2021

**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, 2021 (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 15, 2021

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, 2021 (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 15, 2021

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.
