# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

**WASHINGTON, DC 20549** 

# **FORM 10-Q**

(Mark One)	-			
■ QUARTERLY	Y REPORT PURSUANT TO SECTION 13 OR	15(d) OF THE SECURITIES EXC	HANGE ACT OF 1934	
	For the	e quarterly period ended June 30, 20	021	
		OR		
☐ TRANSITION	N REPORT PURSUANT TO SECTION 13 OR	R 15(d) OF THE SECURITIES EXC	CHANGE ACT OF 1934	
	For the trans	ition period from to		
	Co	ommission File Number: 001-39676		
		SE THERAPEUT	,	
	Delaware		26-3407249	
( State or other jurisdiction of (I.R.S. Employer incorporation or organization) Identification No.)				
	3350 Riverwood Parkway SE, Suite 1900		rucinication 140.)	
	Atlanta, GA		30339	
	(Address of principal executive offices)		(Zip Code)	
	Registrant's telep	hone number, including area code:	(6/8) 392-3419	
Securities registe	ered pursuant to Section 12(b) of the Act:			
	Title of each class	Trading Symbol(s)	Name of each exchange on which registered	
Cor	mmon Stock, \$0.001 par value	IKT	The Nasdaq Stock Market LLC	
	k mark whether the registrant (1) has filed all reports re hat the registrant was required to file such reports), and		f the Securities Exchange Act of 1934 during the preceding 12 morments for the past 90 days. Yes $\boxtimes$ No $\square$	iths (o
	k mark whether the registrant has submitted electronica eding 12 months (or for such shorter period that the reg		be submitted pursuant to Rule 405 of Regulation S-T ( $\S 232.405$ of Yes $\boxtimes$ No $\square$	this
	k mark whether the registrant is a large accelerated filer elerated filer," "accelerated filer," "smaller reporting co		er, smaller reporting company, or an emerging growth company. See in Rule 12b-2 of the Exchange Act.	e the
Large accelerated filer			Accelerated filer	
Non-accelerated filer			Smaller reporting company	$\boxtimes$
			Emerging growth company	$\times$
If an emerging gr	rowth company, indicate by check mark if the registran	t has elected not to use the extended transi	tion period for complying with any new or revised financial accour	nting

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 July 31, 2021, the registrant had 25,133,345 shares of common stock, \$0.001 par value per share, outstanding.

standards provided pursuant to Section 13(a) of the Exchange Act.  $\square$ 

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# PART I—FINANCIAL INFORMATION

# Item 1. Condensed Financial Statements (Unaudited).

# Inhibikase Therapeutics, Inc. Condensed Balance Sheets

	 June 30, 2021		December 31, 2020
	(unaudited)		(Note 3)
Assets			
Current assets:			
Cash	\$ 46,836,556	\$	13,953,513
Grants receivable	586,581		_
Prepaid research and development	958,779		774,356
Prepaid expenses and other current assets	 833,963		54,837
Total assets	\$ 49,215,879	\$	14,782,706
Liabilities and stockholders' equity	 		
Current liabilities:			
Accounts payable	\$ 897,226	\$	1,720,680
Accrued expenses and other current liabilities	872,771		632,934
Deferred revenue	142,619		2,325,741
Notes payable	_		42,534
Total	 1,912,616		4,721,889
Notes payable, net of current portion	248,911		276,461
Total liabilities	2,161,527		4,998,350
Commitments and contingencies (see Note 11)			
Stockholders' equity:			
Preferred stock, \$0.001 par value; 10,000,000 shares authorized at June 30, 2021, and December 31, 2020; 0 shares issued and outstanding at June 30, 2021, and December 31, 2020	_		_
Common stock, \$0.001 par value; 100,000,000 and 30,000,000 shares authorized;			
25,133,345 and 10,050,849 shares issued and outstanding at June 30, 2021 and December 31, 2020, respectively.	25,134		10,051
Additional paid-in capital	67,334,089		24,805,929
Accumulated deficit	(20,304,871)		(15,031,624)
Total	47,054,352		9,784,356
Total liabilities and stockholders' equity	\$ 49,215,879	\$	14,782,706

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

	Three Months Ended June 30,			Six Months Ended June 30,			June 30,	
	2021 2020		2021			2020		
Revenue:								
Grant revenue	\$	1,363,037	\$	219,585	\$	2,770,202	\$	490,372
Total revenue		1,363,037		219,585		2,770,202		490,372
Costs and expenses:								
Research and development		2,382,433		263,175		4,814,293		546,289
Selling, general and administrative		1,608,972		370,331		3,209,548		898,019
Total costs and expenses		3,991,405		633,506		8,023,841		1,444,308
Loss from operations		(2,628,368)		(413,921)		(5,253,639)		(953,936)
Interest expense		(7,811)		(7,948)		(19,608)		(15,373)
Net loss	\$	(2,636,179)	\$	(421,869)	\$	(5,273,247)	\$	(969,309)
Net loss per share – basic and diluted	\$	(0.22)	\$	(0.05)	\$	(0.47)	\$	(0.12)
Weighted-average number of common shares – basic and diluted		12,241,935		8,181,938		11,153,986		8,181,836

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

	Commo	on S	tock						
	Shares		Amount		Additional Paid-In Capital	A	Accumulated Deficit	St	Total ockholders' 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	25,133,345	\$	25,134	\$	67,334,089	\$	(20,304,871)	\$	47,054,352
		_		_		_			
	Commo	n St	ock						
				A	Additional				Total
					Paid-In	A	ccumulated	Sto	ockholders'
	Shares		Amount		Capital		Deficit	Equ	uity (Deficit)
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
Warrent expense	_		_		190,993		_		190,993
Issuance of common stock	874		1		4,870		_		4,871
Net loss			<u> </u>		<u> </u>		(547,440)		(547,440)
Balance 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
Issuance of warrants	_		_		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)

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

		Six Months Ended June 30,			
	2021			2020	
Operating activities					
Net loss	\$	(5,273,247)	\$	(969,309)	
Adjustments to reconcile net loss to net cash used in operating activities:					
Stock-based compensation expense		913,607		279,517	
Non-cash consulting fees		60,391		75,000	
Non-cash PPP loan forgiveness		(27,550)		_	
Warrant expense		477,183		280,509	
Changes in operating assets and liabilities:					
Grants receivable		(586,581)		_	
Prepaid expenses and other assets		(779,126)		(5,640)	
Prepaid research and development		(184,423)		_	
Accounts payable		(837,705)		(211,076)	
Accrued expenses and other current liabilities		239,837		209,149	
Deferred revenue		(2,183,122)		83,508	
Net cash used in operating activities		(8,180,736)		(258,342)	
Financing activities					
Proceeds from notes payable		_		272,800	
Proceeds from issuance of common stock		41,149,608		4,870	
Deferred initial public offering costs		_		(30,000)	
Issuance of common stock from exercise of stock options		34,357		_	
Payment of employee taxes in connection with stock option exercise		(77,652)		_	
Repayments of note payable		(42,534)		_	
Net cash provided by financing activities		41,063,779		247,670	
Net increase (decrease) in cash		32,883,043		(10,672)	
Cash at beginning of period		13,953,513		18,457	
Cash at end of period	\$	46,836,556	\$	7,785	
Supplemental disclosures of cash flow information					
Cash paid for interest	\$	19,608	\$	3,132	
Non-cash financing activities					
Notes payable settled with new notes payable	\$	<u> </u>	\$	42,534	
Notes payable settled with common stock	\$	_	\$	63,800	
PPP loan forgiveness	\$	27,550	\$	_	
Accrued deferred initial public offering costs	\$	_	\$	303,417	

#### Inhibikase Therapeutics, Inc. Notes to Condensed Financial Statements (Unaudited)

#### 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 metabolism of IkT-148009 in human subjects. Outcomes of this study have led to an acceleration of the clinical development program by more than 6 months. 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. We plan to initiate dosing in a Parkinson's patient population in the third quarter of 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 in the third quarter of 2021.

#### 2. Liquidity and Going Concern

The Company has recognized recurring losses. At June 30, 2021, the Company had working capital of \$47,303,263, an accumulated deficit of \$20,304,871, cash of \$46,836,556, accounts payable and accrued expenses of \$1,769,997 and notes payable of \$248,911. The Company had active grants in the amount of \$1,546,730, of which \$772,420 remained available in accounts held by the U.S. Treasury as of April 30, 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 June 30, 2021 is sufficient to fund its normal operations into the first half of fiscal 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") 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 ("FASP")

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 June 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:

	June 30, 2021	De	cember 31, 2020
Accrued consulting	\$ 222,525	\$	115,405
Accrued legal and professional fees			383,286
Accrued research and development	542,189		83,491
Accrued interest	653		1,673
Accrued bonuses	101,907		_
Accrued other	5,497		49,079
Total accrued expenses and other current liabilities	\$ 872,771	\$	632,934

#### 5. Notes Payable

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

	June 202	,	December 31, 2020		
Fifth Restated Note	\$		\$	42,534	
PPP Note		_		27,550	
CEO Restated Note		248,911		248,911	
Total notes payable	\$	248,911	\$	318,995	

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

Year ending December 31,	
2021	\$ _
2022	248,911
2023	_
2024	_
2025	_
Total notes payable	\$ 248,911

### 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.

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 not be repaid for a minimum of 12 months following the closing of its IPO. The principal balance of the CEO Note was \$248,911 at June 30, 2021 and at December 31, 2020 and is included on the condensed balance sheets in Notes payable, net of current portion.

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

On May 4, 2020 the Company received \$27,550 in loan proceeds as part of the Federal CARES 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 six months ended June 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' 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 5,186,570 and 4,318,357 shares of common stock were reserved for issuance upon the exercise of outstanding stock options and warrants as of June 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 six months ended June 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 six months ended June 30, 2021.

During the six months ended June 30, 2020 the Company issued 73,496 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 six months ended June 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. No options were granted during the six months ended June 30, 2020.

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.

Stock-Based Compensation Expense

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

	;	Six Months Ended June 30,				
		2021		2020		
Research and development	\$	480,415	\$	130,041		
Selling, general and administrative		433,192		149,476		
Total stock-based compensation expense	\$	913,607	\$	279,517		

#### 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 six months ended June 30, 2020. There were no warrants issued during the six months ended June 30, 2021. The Company recognized \$237,768 in warrant expense for the six months ended June 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 three months ended June 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:

	Six Months Er	Six Months Ended June 30,			
	2021	2020			
Numerator:					
Net loss	\$ (5,273,247)	\$ (969,309)			
Denominator:					
Weighted-average number of common shares outstanding – basic and diluted	11,153,986	8,181,836			
Net loss per share applicable to common stockholders – basic and diluted	\$ (0.47)	\$ (0.12)			

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:

	Six Months End	ded June 30,
	2021	2020
Options to purchase shares of stock	3,624,657	3,369,144
Warrants to purchase shares of stock	1,561,913	474,723
Total	5,186,570	3,843,867

#### 10. Income Taxes

During the six months ended June 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 of 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 six months ended June 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 From 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. To date, 42 subjects have received IkT-148009. 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. This has led to an acceleration of the clinical development program by more than 6 months. Following agreements with the FDA, we will initiate dosing in a Parkinson's patient population as part of the Phase 1 MAD study in 3Q21. 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 3 months of our chronic toxicology program of IkT-148009 in both rats and monkeys. These toxicology studies will continue for 3 additional months in rats and 6 additional months in monkeys. We have also advanced clinical batch manufacturing and pill formulation for our platform prodrug technology involving IkT-001Pro.

Our programs utilize small molecule, oral protein kinase inhibitors to treat PD and its GI complications. We have shown in animal models of progressive disease that 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. 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 is 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. Based on the measurements in animal models, we believe 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, it is unknown whether the disease modification seen in the animal models will occur in the human disease following treatment with IkT-148009.

In our opinion, the multi-decade failures in the treatment of neurodegenerative diseases such as PD result from a lack of understanding of the biochemistry of the disease processes involved. Neurodegeneration is marked by a progressive degeneration and loss of function of neurons which send and receive signals to and from the brain. Historically, the cause of a neurodegenerative disease was thought to be a "plaque" made up of a misfolded and/or aggregated protein(s). Therapeutic approaches, therefore, sought to remove "plaque" from the brain. A "plaque"-focused treatment strategy has failed to alter the course of Parkinson's disease in two Phase 2 trials that reported results in 2020 and 2021. We believe we are different. We identified the proteins that become

dysfunctional in a disease pathway and sought to understand how a dysfunctional protein causes disease. We believe our approach to PD and other neurological diseases has identified the underlying cause of disease and led to an understanding of how individual proteins are linked together to define the disease process. Using this strategy, we believe we have discovered at least one enzyme that plays a pivotal role in the disease process for PD, the Abelson Tyrosin Kinase c-Abl. We have developed novel protein kinase inhibitors against c-Abl, which we believe can alter the disease course for PD. c-Abl chemically modifies one of the "plaque" proteins in PD, known as alpha-synuclein. Chemical modification creates what we believe to be the true toxic entity of the disease. Treatment with IkT-148009 may prevent chemical modification and, at least in animal models of progressive disease, leads to clearance of the toxic form of alpha-synuclein from the affected neurons.

In addition to programs in PD, our platform drug discovery and delivery technologies have identified additional opportunities, including a potential treatment for bacterial or viral infections in the brain using a single agent at fixed dose, and an oncology opportunity in stable-phase Chronic Myelogenous Leukemia, or CML. Our product for CML, IkT-001Pro, is a prodrug of the anticancer agent Imatinib. A prodrug is a compound that, after administration, is metabolized by the body into a pharmacologically active drug. Imatinib is an FDA designated Orphan Drug and is the standard-of-care treatment for stable-phase CML. In the United States, orphan drug designation entitles a party to incentives such as opportunities for grant funding towards clinical trial costs, tax advantages, and user-fee waivers. We intend to submit an IND to initiate clinical development for IkT-001Pro for the treatment of CML in the third quarter of 2021. Subject to future FDA agreements related to the clinical protocol design and execution of the clinical development program and additional funding, we believe that clinical development of IkT-001Pro could possibly be completed in 2022. We intend to submit a new drug application, or NDA, for IkT-001Pro pursuant to Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act, which specifies the requirements for approval. This pathway would allow us to rely, in part, on data in the public domain or the FDA's prior conclusions regarding the safety and effectiveness of an approved compound. Consistent with FDA guidance on the 505(b)(2) pathway, we will seek input from the FDA as to what should be included in the application prior to submission of the 505(b)(2) application. Pursuit of this oncology opportunity will seek to validate the pharmacology advantages of our prodrug technology in a well understood patient population with an approved drug substance. If we are able to validate IkT-001Pro in oncology, we will evaluate whether the pharmacology advantages we discover about IkT-001Pro could be a

We believe we are one of the pioneers of the application of protein kinase inhibitors to non-oncology indications, including neurodegeneration and infectious diseases, as well as their more traditional role in the treatment of cancer. As of the date of this Report, more than \$20 million of the Company's total funding has been received from Private, State and Federal granting agencies, including the National Institutes of Health, the Department of Defense and the Michael J. Fox Foundation, with the approximately \$55.7 million raised from public offerings of our common stock. Private, State and Federal granting agencies use extensive scientific peer review in deciding which projects to fund that could impact human disease. We believe our ability to advance the Company on the basis of scientific peer review reflects the potential our scientific peers see for the possible success of our therapeutic programs.

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. We further intend to advance IkT-001Pro through clinical development, possibly completing clinical development in 2022.

#### **Our Programs**

Our portfolio is focused on developing protein kinase inhibitors to treat PD in the brain and GI tract that arise from dysfunctional alpha-synuclein in PD patients. Using IkT-148009, we intend to clinically evaluate the impact of c-Abl inhibition on newly diagnosed PD patients, patients early in the course of PD, and PD patients with GI complications. We are pursuing clinical development using a sequential Phase 1/ Phase 2 development approach, with the details of the Phase 2 studies subject to agreements with the FDA regarding trial design and the outcome of the Phase 1 clinical trial. The Phase 1/Phase 2 development program, subject to FDA approval, would be followed with one or more Phase 3 clinical trials that we believe could lead to completion of the clinical development program in 2023 or 2024. IkT-148009 is intended to treat PD in treatment-naïve and early-stage PD patients, along with GI complications such as difficulty in swallowing, or dysphagia, and for treatment of neurogenic constipation.

In addition to programs in PD, our platform drug discovery and delivery technologies have identified additional opportunities, including a potential treatment for bacterial or viral infections in the brain using a single agent at fixed dose, and an oncology opportunity in stable-phase Chronic Myelogenous Leukemia, or CML. Our product for CML, IkT-001Pro, is a prodrug of the anticancer agent Imatinib. A prodrug is a compound that, after administration, is metabolized by the body into a pharmacologically

active drug. Imatinib is an FDA designated Orphan Drug and is the standard-of-care treatment for stable-phase CML. In the United States, Orphan Drug designation entitles a party to incentives such as opportunities for grant funding towards clinical trial costs, tax advantages, and user-fee waivers. We remain on track to submit an IND to initiate clinical development for IkT-001Pro in the third quarter of 2021. Subject to future FDA agreements related to the clinical protocol design and execution of the clinical development program and additional funding, we believe that clinical development of IkT-001Pro could possibly be completed in 2022. We intend to submit a new drug application, or NDA, for IkT-001Pro pursuant to Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act, which specifies the requirements for approval. This pathway would allow us to rely, in part, on data in the public domain or the FDA's prior conclusions regarding the safety and effectiveness of an approved compound. Consistent with FDA guidance on the 505(b)(2) pathway, we will seek input from the FDA as to what should be included in the application prior to submission of the 505(b)(2) application. Pursuit of this oncology opportunity will seek to validate the pharmacology advantage of our prodrug technology in a well understood patient population with an approved drug substance. If we are able to validate IkT-001Pro in oncology, we will evaluate whether the pharmacology advantages we discover about IkT-001Pro could be applied to novel drug substances, such as IkT-148009.

Additional research programs will seek to develop medications for other alpha-synuclein-related diseases, specifically Dementia with Lewy Body, or DLB, and Multiple System Atrophy, or MSA, as well as our programs in anti-infectives that target host-factors to block viral or bacterial infections in the brain with a single agent at fixed dose. Our first application intends to treat infectious disease by suppressing John Cunningham virus, or JCV, virus infection, the cause of Progressive Multifocal Leukoencephalopathy, or PML.

#### **Components of Operating Results**

#### **Operating Expenses**

Research and Development

Research and development activities account for a significant portion of our operating expenses. Research and development expenses accounted for 26% and 37% of our operating expenses for the years ended December 31, 2020 and 2019, respectively. 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 investigational new drug ("IND") and new drug applications ("NDA") with the FDA;
- our ability to conduct and commence trials;
- · our ability to establish an appropriate safety profile with IND-enabling toxicology studies;

- · our ability to successfully develop, obtain regulatory approval for, and then successfully commercialize, our product candidates;
- our successful enrollment in and completion of our current and future clinical trials;
- the costs associated with the development of any additional product candidates we identify in-house or acquire through collaborations;
- our ability to discover, develop and utilize biomarkers to demonstrate target engagement, pathway engagement and the impact on disease progression of our molecules:
- our ability to establish agreements with third-party manufacturers for clinical supply for any future clinical trials and commercial manufacturing, if our product candidates are approved;
- the terms and timing of any collaboration, license or other arrangement, including the terms and timing of any milestone payments thereunder;
- our ability to obtain and maintain patent, trade secret and other intellectual property protection and regulatory exclusivity for our product candidates if and when approved;
- our receipt of marketing approvals from applicable regulatory authorities;
- the impact of the outbreak of the novel coronavirus disease, COVID-19, pandemic which has had an adverse impact on our business, including our
  preclinical studies and clinical trials;
- · 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 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 June 30, 2021 and 2020

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

	For the Three Months Ended June 30,				Change		
	2021		2020		(\$)		(%)
		(unaud	ited)				
Grant revenue	\$	1,363,037	\$	219,585	\$	1,143,452	520.7
Research and development		(2,382,433)		(263,175)		(2,119,258)	805.3
Selling, general and administrative		(1,608,972)		(370,331)		(1,238,641)	334.5
Loss from operations		(2,628,368)		(413,921)		(2,214,447)	(535.0)
Interest expense, net		(7,811)		(7,948)		137	(1.7)
Net loss	\$	(2,636,179)	\$	(421,869)	\$	(2,214,310)	(524.9)

#### Grant Revenue

Grant revenue for the three months ended June 30, 2021, increased by \$1,143,452 or 521% to \$1,363,037 from \$219,585 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 resources in 2021 to carry on its Phase I clinical trials in addition to its grant research activity.

#### Research and Development

Research and development expenses increased by \$2,119,258 or 805% to \$2,382,433 from \$263,175 in the prior year comparable period. The increase was driven by a \$1.0 million increase in grant related research expenditures and a \$1.1 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 \$1,238,641 or 335% to \$1,608,972 from \$370,331 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 \$0.3 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 \$0.5 million for other normal operating expenses.

#### Interest Expense

Interest expense decreased by \$137 or 2% to \$7,811 from \$7,948 in the prior year comparable period. The increase was driven by financing of insurance premiums during the three months ended June 30, 2021. The Company experienced normal but significant increases in insurance premiums during the first three months of 2021 after its December 31, 2020 IPO. In the prior year, comparable period insurance premiums were not financed.

#### Comparison of the Six Months Ended June 30, 2021 and 2020

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

	For the Six Months Ended June 30,				Change		
		2021		2020		(\$)	(%)
	(unaudited)						
Grant revenue	\$	2,770,202	\$	490,372	\$	2,279,830	464.9
Research and development		(4,814,293)		(546,289)		(4,268,004)	781.3
Selling, general and administrative		(3,209,548)		(898,019)		(2,311,529)	257.4
Loss from operations		(5,253,639)		(953,936)		(4,299,703)	450.7
Interest expense, net		(19,608)		(15,373)		(4,235)	27.5
Net loss	\$	(5,273,247)	\$	(969,309)	\$	(4,303,938)	444.0

Grant Revenue

Grant revenue for the six months ended June 30, 2021, increased by \$2,279,830 or 465% to \$2,770,202 from \$490,372 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 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 \$4,268,004 or 781% to \$4,814,293 from \$546,289 in the prior year comparable period. The increase was driven by a \$2.1 million increase in grant related research expenditures and a \$2.1 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 \$2,311,529 or 257% to \$3,209,548 from \$898,019 in the prior year comparable period. The increase was primarily the result of increased non-cash stock compensation expense of \$0.5 million, increased director and officer's liability insurance of \$0.7 million related to the Company's initial public offering in December 2020, increased legal fees, board fees, investor relation and consulting fees of \$0.6 million relating to operating as a public company registrant since December 2020 and a net increase of \$0.5 million for other normal operating expenses.

#### Interest Expense

Interest expense increased by \$4,235 or 28% to \$19,608 from \$15,373 in the prior year comparable period. The increase was driven by financing of insurance premiums during the six months ended June 30, 2021. The Company experienced normal but significant increases in insurance premiums during the first six months of 2021 after its December 31, 2020, initial public offering. In the prior year comparable period insurance premiums were not financed.

#### **Liquidity and Capital Resources**

#### Sources of Liquidity

From our inception through June 30, 2021, we have funded our operations primarily through private, state and federal contracts and grants. From our inception through June 30, 2021, we generated aggregate cash proceeds of approximately \$20.4 million from private, state and federal contracts and grants. In addition, 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 June 30, 2021, the Company had working capital of \$47,303,263, an accumulated deficit of \$20,304,871, cash of \$46,836,556, and accounts payable and accrued expenses of \$1,769,997 The Company had active grants in the amount of \$1,546,730, of which \$772,420 remained available in accounts held by the U.S. Treasury as of April 30, 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 2022.

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 \$20,304,871 at June 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 \$47,303,263 at June 30, 2021 and active grants in the amount of \$1,546,730, of which \$772,420 remained available in accounts held by the U.S. Treasury as of April 30, 2021. The Company estimates that its working capital at June 30, 2021 is sufficient to funds it normal operations into the first half of fiscal 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:

	Six Months l	Six Months Ended June 30,			
	2021		2020		
Net cash used in operating activities	\$ (8,180,736)	\$	(258,342)		
Net cash provided by financing activities	41,063,779		247,670		
Net increase (decrease) in cash	\$ 32,883,043	\$	(10,672)		

#### Net Cash Flows Used in Operating Activities

Net cash flows used in operating activities for the six months ended June 30, 2021, totaled \$8,180,736, and consisted primarily of a net loss of \$5,273,247 adjusted for non-cash stock compensation of \$913,607, non-cash warrant expense of \$477,183, non-cash consulting fees of \$60,391, non-cash PPP Loan forgiveness of \$27,550, a decrease of \$184,423 in prepaid research and development, an increase in prepaid expenses and other assets of \$779,126, a decrease in accrued expenses and other current liabilities of \$239,837, a decrease in accounts payable of \$837,705 and a decrease in deferred revenue of \$2,183,122 and an increase in grants receivable of \$332,774.

Net cash flows used in operating activities for the six months ended June 30, 2020, totaled \$258,342, and consisted primarily of a net loss of \$969,309 adjusted for non-cash stock compensation of \$279,517, non-cash warrant expense of \$280,509, non-cash consulting fees of \$75,000, a decrease in prepaid expenses of \$5,640, a decrease in accounts payable of \$211,076, an increase in accrued expenses of \$209,149, and an increase in deferred revenue of \$83,508.

#### Cash Provided by Financing Activities

Net cash flows provided by financing activities for the six months ended June 30, 2021, totaled \$41,063,779, which primarily consisted of cash flows from capital raise of \$41,149,608.

Net cash flows provided by financing activities for the six months ended June 30, 2020, totaled \$247,670, which consisted of proceeds of \$245,250 from the issuance of a note payable and \$4,870 from the issuance of common stock.

#### 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<sup>TM</sup> 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 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(e) and 15d-15(e) 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 June 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 six months ended June 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 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.

#### Item 3. Defaults Upon Senior Securities.

None.

#### Item 4. Mine Safety Disclosures.

Not applicable.

# Item 5. Other Information.

None.

#### Item 6. Exhibits.

			Incorporated by Reference to SEC Filing		
Exhibit		-	Exhibit	•	
No.	Filed Exhibit Description	Form	No.	File No.	Date Filed
3.1	Amended and Restated Certificate of Incorporation of Inhibikase Therapeutics,	8-K	3.1	001-39676	12/29/2020
	Inc., as most recently amended and restated effective Wednesday, December 23,				
	<u>2020</u> .				
3.2	Amended and Restated Bylaws of Inhibikase Therapeutics, Inc., as most recently	8-K	3.2	001-39676	12/29/2020
	amended and restated effective Wednesday, December 28, 2020.				
10.1	<u>Underwriting Agreement dated June 15, 2021 by and between Inhibikase</u>	8-K	1.1	001-39676	6/16/2021
	Therapeutics, Inc. and ThinkEquity, a division of Fordham Financial				
	Management, Inc., as representative of the underwriters listed on Schedule 1				
	thereto.				
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)				

 <sup>\*</sup> Filed 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.

<sup>\*\*</sup> Furnished herewith.

# **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 Ther	Inhibikase Therapeutics, Inc.			
Date: August 16, 2021	Ву:	/s/ MILTON H. WERNER, Ph.D.			
		Milton H. Werner, Ph.D.			
		Chief Executive Officer			
		(Principal Executive Officer)			
Date: August 16, 2021	Ву:	/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: August 16, 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: August 16, 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 June 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: August 16, 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 June 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: August 16, 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.