



**Inhibikase
Therapeutics**

2023 Annual Report

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM 10-K

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended **December 31, 2023**

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

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES NO

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act YES NO

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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report.

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements.

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b).

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). YES NO

The aggregate market value of the common stock, par value \$0.001 per share, ("Common Stock") held by non-affiliates of the Registrant, based on the closing price of the shares of Common Stock on The Nasdaq Stock Market on June 30, 2023 (the last business day of the Registrant's most recently completed second fiscal quarter) was \$19.1 million. Shares of the Registrant's common stock held by each executive officer, director and holder of 5% or more of the outstanding Common Stock have been excluded in that such persons may be deemed to be affiliates. This calculation does not reflect a determination that certain persons are affiliates of the registrant for other purposes. The number of shares of the Registrant's Common Stock outstanding as of March 15, 2024 was 6,476,844.

DOCUMENTS INCORPORATED BY REFERENCE

None

Table of Contents

	<u>Page</u>
PART I	
Item 1. Business	2
Item 1A. Risk Factors	26
Item 1B. Unresolved Staff Comments	76
Item 1C. Cybersecurity	76
Item 2. Properties	77
Item 3. Legal Proceedings	77
Item 4. Mine Safety Disclosures	77
PART II	
Item 5. Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	78
Item 6. [Reserved]	78
Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations	79
Item 7A. Quantitative and Qualitative Disclosures About Market Risk	88
Item 8. Financial Statements and Supplementary Data	88
Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure	88
Item 9A. Controls and Procedures	88
Item 9B. Other Information	88
Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections	88
PART III	
Item 10. Directors, Executive Officers and Corporate Governance	89
Item 11. Executive Compensation	98
Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	104
Item 13. Certain Relationships and Related Transactions, and Director Independence	105
Item 14. Principal Accounting Fees and Services	106
PART IV	
Item 15. Exhibits, Financial Statement Schedules	F-1
Item 16. Form 10-K Summary	F-3
Signatures	F-4

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

All statements included or incorporated by reference in this Annual Report on Form 10-K, or the 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, some of which are listed under "Risk Factors" in Item 1A of this Report. 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. In this Report, unless otherwise indicated, the "Company", "we," "us" or "our" refer to Inhibikase Therapeutics, Inc., a Delaware corporation and its subsidiary, IKT Securities Corporation, a Massachusetts corporation.

The sources of industry and market data contained in this financial report primarily include those listed below:

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9. Ying Zhao, et al., "Progression of Parkinson's Disease as Evaluated by Hoehn and Yahr Stage
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2. W. Dauer, S. Przedborski, Parkinson's Disease: mechanisms and models. *Neuron*. 39, 889-909 (2003).
3. M. Goedert, α -Synuclein and neurodegenerative diseases. *Nat Rev Neurosci*. 2, 492-501 (2001).
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7. Werner MH and Olanow CW. Parkinson's disease modification through c-Abl inhibition: An Opportunity. *Mov. Disorder* 2022; 37:6-15.
8. Karuppagounder, et al. The c-Abl Inhibikase Risvodetinib suppresses neurodegeneration in murine models of heritable and sporadic Parkinson's disease. *Sci. Transl. Med.* 2023;15:eabp9352.
9. Marmion, et al. Viral-based rodent and nonhuman primate models of multiple system atrophy: Fidelity to the human disease. *Neuro. Biol. Dis.* 2021: 148:105184.

PART I

Item 1. Business.

Company Overview

We are a clinical-stage pharmaceutical company developing protein kinase inhibitor therapeutics to modify the course of Parkinson's disease ("PD"), Parkinson's-related disorders and other diseases of the Abelson Tyrosine Kinases. The Company's multi-therapeutic pipeline has a primary focus on neurodegeneration and its lead program utilizing Risvodetinib (also known as IkT-148009), a selective inhibitor of the non-receptor Abelson Tyrosine Kinases, targets the treatment of Parkinson's disease inside and outside the brain as well as other diseases that arise from Abelson Tyrosine Kinases. In 2021, we commenced clinical development of Risvodetinib (IkT-148009), which we believe can modify the course of Parkinson's disease including its manifestation in the gastrointestinal tract, or GI. In January, 2023, the Company initiated its Phase 2 program, termed 'the 201 trial' (www.the201trial.com), for Risvodetinib (IkT-148009) as a treatment for Parkinson's disease and began the process of opening up to 34 sites in the U.S. As of March 22, 2024, 32 sites are open and actively evaluating prospective trial participants. 73 participants have been enrolled, 20 prospective participants are in medical screening and 48 potential participants are being evaluated for suitability to initiate medical screening. Thirty-four participants have completed the 12-week dosing period. As of March 22, 2024, 15 mild and two moderate possibly treatment-related adverse events have been reported across all enrolled patients taking Risvodetinib (IkT-148009). Depending on the timing of the last enrolled patient, results from this trial may be reported in the second-half of 2024. Monthly site enrollments have increased month-over-month since our patient outreach program was initiated. As such, we believe a more rapid path to enrollment is emerging through the public outreach/awareness campaign led by the 'the201trial.com' website. The emerging path to complete enrollment has prompted us to take further advantage of this multi-dose study by planning to extend the 201 trial by an additional 12 months, subject to additional resources.

The twelve-week 201 trial is evaluating three doses in participants who have untreated Parkinson's disease on a staggered schedule and is placebo controlled with 1:1:1:1 randomization. The primary endpoints of this trial are safety and tolerability and a hierarchy of 15 secondary endpoints will evaluate treatment benefit in the brain and GI tract. The recent analysis of 11 patients who participated in the 201 trial prior to the temporary clinical hold issued by the U.S. Food and Drug Administration ("FDA") in November, 2022, which was lifted in January, 2023, suggested that Risvodetinib (IkT-148009) may have some effect on disease. These participants were withdrawn from the trial following the FDA's temporary clinical hold. As detailed at the Movement Disorder Society Congress held August 2023, the primary secondary endpoint is a functional assessment comprised of the sum of Parts 2 and 3 of the Movement Disorder Society Universal Parkinson's Disease Rating Scale (MDS-UPDRS Parts II+III). This sum showed an average -8.7 point improvement in the three participants on the 200 mg dose relative to baseline, while three placebo participants increased by +1.7 points; this represents an average spread of -10.4 points. A lower (or negative) change relative to placebo of greater than -3 to -6 points might be considered a measure of improvement. Given the small sample size on this dose, we believe it is premature to conclude a clinical benefit, but this observation reinforces our desire to extend the trial for an additional 12 months to potentially obtain a clear picture of clinical benefit over a total measurement of 15 months.

In March 2023, we opened our IND for Risvodetinib (IkT-148009) as a treatment for the Parkinson's-related orphan disease Multiple System Atrophy, or MSA. Our evaluation of Risvodetinib (IkT-148009) in MSA was benefited by a grant received from the National Institute of Neurological Diseases and Stroke, an Institute of the National Institutes of Health, for \$0.39 million to fund animal model studies of Risvodetinib (IkT-148009) as a therapy for MSA. Two different animal studies were undertaken to evaluate whether Risvodetinib (IkT-148009) could have an impact on disease in the animal. One model evaluated the ability of Risvodetinib (IkT-148009) to modify disease early in its progression, while the second model is evaluating whether Risvodetinib (IkT-148009) can correct functional loss much later in the disease course. The early progression model study has now been shown to preserve nearly normal functional activity following 20 weeks of once daily dosing relative to untreated controls. Preservation of function in this model occurred with substantial reduction of the underlying alpha-synuclein pathology. The second model evaluating Risvodetinib (IkT-148009) late in the disease course is ongoing. In addition, Risvodetinib (IkT-148009) was recently given Orphan Drug Designation by the FDA for the treatment of MSA. We plan to initiate a Phase 2 study in MSA patients in up to nineteen sites in the EU, and up to six sites in the U.S. involving at least 120 patients, and we are presently seeking non-dilutive resources to initiate and execute this trial in its entirety. The proposed Phase 2 study will have primary endpoints in safety, tolerability and efficacy following once daily dosing at two dose levels for 12-months. We plan to submit complementary regulatory documents for Risvodetinib (IkT-148009) to European Union authorities in 2024.

We are also developing platform technologies to improve delivery of protein kinase inhibitors in patients. One example of our potential ability to improve drug delivery is IkT-001Pro, a prodrug of the anticancer agent imatinib mesylate, which is intended to treat Stable Phase Chronic Myelogenous Leukemia, or SP-CML. IkT-001Pro has completed a three-part dose finding/dose equivalence study in 66 healthy volunteers (known as 'the 501 trial'). The study was designed to evaluate the 96-hour pharmacokinetics of imatinib delivered as IkT-001Pro and determine the dose of IkT-001Pro that can deliver the equivalent of either 400 mg or 600 mg imatinib mesylate. As of the date of this Report, bioequivalence to 400 mg imatinib mesylate has been established to our satisfaction for a 600 mg dose of IkT-001Pro. We further evaluated 600 mg imatinib mesylate and believe that a 900 mg dose

of IKT-001Pro is the preferred dose of IKT-001Pro to deliver a dose of imatinib equivalent to 600 mg imatinib mesylate. We studied 800 mg IKT-001Pro and found it to be nearly equivalent to 600 mg imatinib mesylate. We intend to study higher doses of IKT-001Pro to cover the full range of doses approved for imatinib mesylate to treat up to 11 adult and pediatric blood cancers.

On January 19, 2024, members of the Company along with its medical oncology consultants met with the FDA Review Team (the “Review Team”) from the Division of Hematologic Malignancies in a Pre-NDA meeting to discuss our bioequivalence studies of IKT-001Pro and its path to approval. All questions were addressed and summarized in official meeting minutes issued by the FDA on February 12, 2024. During the meeting we inquired whether additional clinical studies may be needed to seek approval and discussed manufacturing and quality control requirements for approval. The Review Team acknowledged that the 505(b)(2) pathway appears to be the appropriate pathway for approval of IKT-001Pro and indicated that, pending formal review of our clinical data, clinical studies completed to date indicate that 600 mg and 800 mg IKT-001Pro provides similar exposures to 400 mg and 600 mg imatinib mesylate, respectively, subject to review of the NDA upon filing. In addition, given that imatinib mesylate is approved for use between 300 mg and 800 mg once daily for a variety of blood and gastrointestinal cancers, the Review Team stated that if we intend to seek approval across all currently approved indications, we should evaluate additional dose(s) as needed to measure the safety, tolerability and bioequivalent dose of IKT-001Pro that would deliver up to 800 mg, the highest approved dose of imatinib mesylate. The Review Team also discussed the possible difference between IKT-001Pro and imatinib mesylate absorption in the gut and recommended that we evaluate whether IKT-001Pro and imatinib mesylate behave differently with respect to certain gut transporters that regulate absorption. We are in alignment with the FDA and are initiating the necessary pre-clinical test to evaluate this further to ensure that delivery of imatinib by IKT-001Pro mimics imatinib mesylate in all respects. Finally, a number of recommendations were discussed to prevent the potential mix-up between 001Pro and imatinib mesylate either at the pharmacy or by patients for two drugs delivering the same active ingredient. We discussed alternate dosage forms for IKT-001Pro relative to imatinib mesylate as the primary mitigation strategy and will provide a justification of the dosage forms chosen and why they are unlikely to cause medication errors. To ensure that we meet the manufacturing requirements for approval, we will request milestone-based meetings with the Review Team as we complete the required manufacturing and quality control processes.

A second example of our potential ability to improve drug delivery through formulation development is the tablet formulation of Risvodetinib (IKT-148009), which we measured to nearly double the concentration of Risvodetinib (IKT-148009) delivered relative to the same dose previously administered as a gelatin capsule. This provides the opportunity to lower the effective oral dose, which could lead to further safety and tolerability improvements for Risvodetinib (IKT-148009). The Company plans to introduce the tablet formulation into the 12-month extension study, once implemented, as well as in all future clinical trials.

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 and published those results in several high-profile peer reviewed publications. 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. We believe our approach to neurodegenerative disease is validated by our 2022 and 2023 publications and oral presentations at the major academic and industry conferences in Parkinson’s and Alzheimer’s diseases.

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

We currently have worldwide commercialization rights to all of our development programs and IP protection until 2033 for IKT-001Pro and 2036 for Risvodetinib (IKT-148009). Additional filings could extend this period of exclusivity longer.

RAMP™: Our Reengineering Approach with Metabolism Preserved

Our candidate portfolio relies on our medicinal chemistry design approach which evaluates the human pharmacology of an approved drug and uses the approved drug as a template on which to base a novel drug design. Key to this proprietary process is the reproduction of the metabolism of the template in the new molecule. By preserving the metabolic process and generating metabolites in the new molecule that match the metabolites of the template, we believe the safety profile of the new molecule will be

nearly the same as the template. We believe the safety profile will be the same because most side effects arise from the chemical structure, i.e., the drug's selectivity for the target and the metabolites of the drug. When the metabolites of the template and the new molecule chemically match, there is a high likelihood that the safety profile of the new molecule will be similar to or the same as the safety profile of the template. We validated this was the case for Risvodetinib (IkT-148009), our lead molecule for PD and related disorders, which used imatinib as a design template. Imatinib is the active ingredient in the anti-cancer drug Gleevec®, whose side effect profile linearly correlates with its oral dose. With metabolite matching between Risvodetinib (IkT-148009) and imatinib, we believe we can take advantage of the linear correlation between side effects and oral dose because Risvodetinib (IkT-148009) is 25-fold more potent than imatinib against its therapeutic target, predicting a dose that will be lower than the standard dose of imatinib (400 mg) and predicting a human safety profile that is expected to be no worse than that of imatinib. While the clinical data is still preliminary for Risvodetinib (IkT-148009), Risvodetinib (IkT-148009) appears to have a more favorable safety and tolerability profile than the template used to design it.

Our Portfolio

Risvodetinib: Our product candidate for Parkinson's Disease and related alpha-synuclein disorders

Market and Commercial Opportunity

Parkinson's disease (PD) is the second most prevalent neurodegenerative disorder, affecting 900,000 to 1,300,000 persons in the United States, with 90,000 new cases and 38,000 deaths annually with an average age of onset of 60 years of age. In addition to the 60,000 new cases each year, thousands of cases are thought to go undetected. Worldwide, there could be as many as 10,000,000 cases of PD. By 2030, PD drug treatment costs are expected to exceed \$12.2 billion. The country with the highest- diagnosed prevalence of PD is the U.S. PD tends to be a disease of men, with a nearly 2:1 ratio of men:women among patients diagnosed with this disease. A particular challenge to the treatment of Parkinson's patients are their comorbidities, which include arthritis, cardiovascular disease, psychoses and dementia. Since our products would be used to treat PD and its GI complications, we believe we have multiple opportunities to achieve commercial success in several treatment areas in this market.

c-Abl inhibition as a treatment focus in PD and related diseases.

PD is a progressive disorder characterized by tremors, rigidity, difficulty in walking and an inability to maintain one's posture or keep oneself from falling.^{1, 2} Pathologically, PD is characterized by degeneration of neurons in an area of the brain near the brainstem, coupled with the clumping and accumulation of misfolded proteins in cell bodies known as Lewy bodies (LBs)^{3,4,5}. The clinical and pathologic features of PD affect other areas of the brain in addition to the brainstem, resulting in a widespread pathology that is not adequately controlled with dopamine-replacement (i.e. levodopa) therapy.⁶ Manifestations of PD include falling, freezing, neuropsychiatric disorders, GI complications, sensory problems, and cognitive impairment with dementia.⁶ PD is initiated by a dysfunctional protein known as alpha-synuclein. In its dysfunctional form, alpha-synuclein is aggregated and likely to be misfolded, which alters its physiological properties in the body. Dysfunctional alpha-synuclein, when taken up by a neuron, starts a cascade of events that are illustrated in Fig. 1.⁷

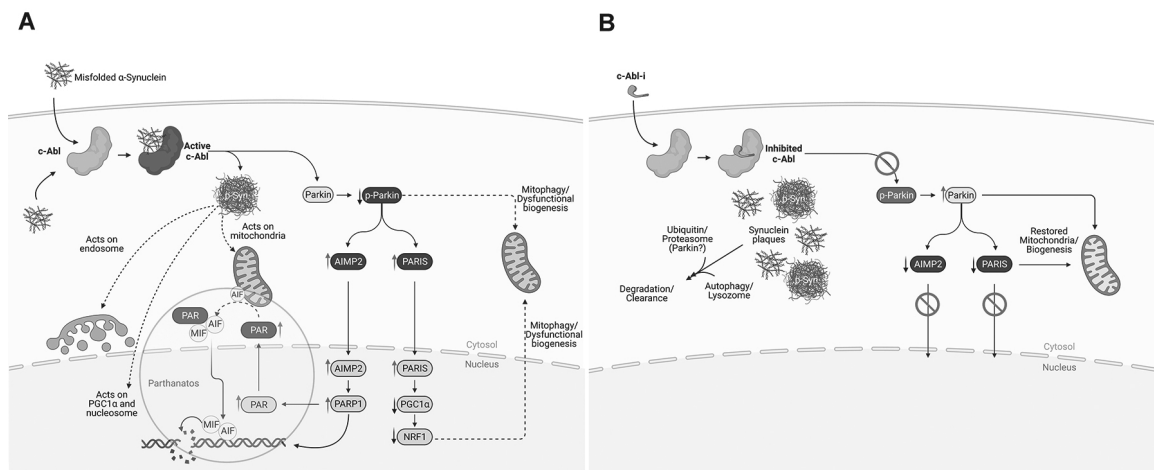


Fig. 1: The Biochemistry of Parkinson's Disease Initiation and Progression and How to Disrupt It

A. The process of neurodegeneration. Misfolded α -synuclein can arise from a variety of factors (see text). Misfolded α -synuclein may form within the neuron or by transfer through cell surface receptors or by crossing membrane bilayers. Within a neuron, misfolded α -synuclein is 'sensed' and c-Abl activated, driving the formation of pathologic α -synuclein by chemical modification (p-Syn). Chemical modification creates a form of α -synuclein that represents the pathologic species of the disease leading to disruption of mitochondrial integrity, negatively impact the endosome, disrupt nucleosomal structure and modulate transcription of certain genes. C-Abl also inactivates parkin by chemical modification, which affects mitochondrial quality control and suppresses protein clearance mechanisms. Parkin inactivation suppresses the complex interplay between parkin and pink1 at the mitochondrion, which act in concert to maintain mitochondrial integrity, quality and regulate mitochondrial biogenesis. Parkin inactivation leads to the accumulation of toxic parkin substrates PARIS (PARKin Interacting Substrate), aminoacyl tRNA synthetase complex-interacting multifunctional protein 2 (AIMP2) and far upstream element-binding protein 1 (FBP1), (AIMP2) and far upstream element-binding protein 1 (FBP1). PARIS and AIMP2 accumulate in adult conditional parkin knockout mice and MPTP-intoxicated mice as well as in patients with PD. Increased levels of PARIS can lead to mitochondrial dysfunction through down-regulation of PGC-1 α and loss of DA neurons in a PARIS-dependent manner. Over expression of AIMP2 leads to an age-dependent, selective degeneration of DA neurons through activation of poly (ADP-ribose) polymerase 1 (PARP1), driving PARP1-mediated parthanatos. This suggests that PARIS and AIMP2 may be important contributors to the loss of DA neurons and possibly other vulnerable neurons following parkin inactivation. Inactivation of parkin also disrupts protein clearance mechanisms through autophagy, lysosomal and proteasomal degradation pathways.

B. The consequences of c-Abl inhibitor treatment on the process of neurodegenerative disease. Inhibition of c-Abl precludes c-Abl activation, blocking the build-up of toxic parkin substrates PARIS and AIMP2 and terminating downstream events. This also re-establishes normal mitochondrial quality control and biogenesis. Model studies demonstrate that modified and unmodified α -synuclein aggregates are shunted to lysosomal or proteasomal degradation pathways for clearance with concomitant recovery of motor function.

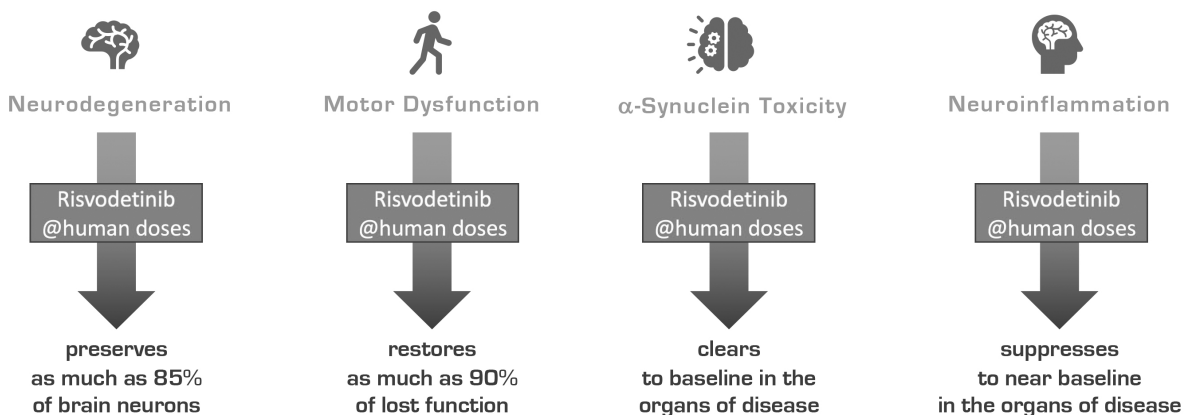
We believe that we can succeed in developing therapies that will slow or stop PD and related disorders because we and our collaborators have characterized the pathways in Fig. 1. We believe the Abelson tyrosine kinase, or c-Abl, acts as a checkpoint on the pathway driving neurodegeneration. The steps on the pathway illustrated in Fig. 1 have been validated in multiple contexts and multiple organ systems and by reproducing parts of these results in preclinical animal models in three independent laboratories. Drawing from this knowledge, we believe inhibition of c-Abl will block the events downstream of c-Abl in these pathways and modify disease for PD and other alpha-synuclein related disorders.

Risvodetinib (IkT-148009) for neurodegenerative disease

Prophylactic and Therapeutic Efficacy of Risvodetinib (IkT-148009) in Murine Models of Human Parkinson's disease

In 2023, we published the outcomes of a series of studies demonstrating that Risvodetinib (IkT-148009) can prevent neurodegeneration in animal models of acute neurotoxicity, and can therapeutically treat Parkinson's in animal models of inherited or sporadic disease.⁸ As illustrated in Figure 2, oral, 1x/day treatment with doses of Risvodetinib (IkT-148009) that are the same doses as proposed to be given humans halts disease progression, blocks neurodegeneration and restores lost function while simultaneously clearing the underlying alpha-synuclein pathology from the affected tissue.

Fig. 2: Therapeutic outcomes of once daily Risvodetinib therapy in murine models of human Parkinson's disease⁸



Clinical Development of Risvodetinib (IkT-148009)

Risvodetinib (IkT-148009) has been evaluated in single dose studies between 12.5 mg and 325 mg given once daily to older and elderly healthy adults aged 45-70 and in 7-day repeat dose studies between 12.5 mg and 200 mg given once daily to older and elderly healthy adults as well as to participants with Parkinson's disease who remained on their anti-Parkinsonian medications. A total of 36 adverse events were observed across 119 individuals, just 12 that could have been treatment related to Risvodetinib (IkT-148009) were reported. All adverse events seen were mild in severity and none of clinical significance. With dosing durations of up to 12 weeks once daily, Risvodetinib (IkT-148009) appears to be safe and well-tolerated for the doses and treatment durations evaluated to

date. Risvodetinib (IkT-148009) has not induced cardiovascular, hematological or gastrointestinal side effects of any significance and does not exacerbate orthostatic hypotension common to Parkinson’s disease nor does it induce QTcF prolongation effects common to many protein kinase inhibitors.

Pharmacokinetically, the maximum plasma concentration or C_{max} , and the Area Under the time-Concentration curve (AUC) increases linearly with dose, but these increases are less than dose proportional above 75 mg once daily. Risvodetinib (IkT-148009) has a long half-life (\approx 24 hrs), does not accumulate on repeat dosing and reaches steady-state above 50 mg on the first dosing day. The therapeutic dosing range was established by comparison of the steady-state C_{max} and AUC observed in efficacy animals to the pharmacokinetics of single and multiple doses given once daily to human beings. This comparison established the therapeutic dosing range to be 50 mg to 200 mg and formed the basis for the doses being explored in the ongoing Phase 2 trial, known as the 201 Trial in Untreated Parkinson’s disease.

The 201 Trial is a two part study in which participants in Part 1 with untreated Parkinsons’ disease will be administered 50, 100 or 200 mg Risvodetinib (IkT-148009) or placebo once daily for 12 weeks. In animal model studies, functional recovery was rapid, with recovery in the gastrointestinal tract within 4 weeks and recovery in the brain within 8 weeks, supporting the use of 12 weeks as the initial clinical evaluation period for therapeutic evaluation in the 201 Trial.⁸

The planned Part 2 of the 201 Trial is a 12 month extension study in which the participants on placebo will be switched to the 200 mg dose and all other participants will stay on the same dose as they were during Part 1. The blind will be maintained for all participants and clinicians through both parts. The design will satisfy the need to demonstrate 3 month safety/tolerability in this patient population before launch into long-term studies, while simultaneously evaluating a hierarchy of 15 measures of motor and non-motor function in the brain and gastrointestinal tract to evaluate clinical benefit. During the 12-month extension study, clinical benefit will continue to be measured quarterly, resulting in 15 months of measures of clinical benefit. We project that the 12 week period will be fully enrolled before the end of the third quarter, 2024 or earlier. The planned Part 2 of the 201 Trial will initiate once adequate resources are secured.

The expansion of the 201 Trial to the 12 month extension study is supported, in part, by the outcomes measured in 11 patients (8 active, 3 placebo) measured in untreated Parkinson’s disease for up to 11 weeks in the participants pulled from the trial following a temporary FDA stoppage of the 201 trial in 2022 (Table 1).

Table 1: Measure of therapeutic outcomes of once daily Risvodetinib therapy in participants with Parkinson’s disease up to 11 weeks.

Assessment	Mean Change from Baseline @ 4 weeks				Mean Change from Baseline @ End of Study			
	50 mg N=3	100 mg N=2	200 mg N=2	Placebo N=3	50 mg N=3	100 mg N=2	200 mg N=3	Placebo N=3
PGI-S	-0.33	0	-1	-0.33	0	0	0	-0.33
CGI-S	0.33	-0.5	-2	-0.33	0.33	-2	-0.67	-0.33
PDQ-39	-1	0	-3.5	-8.3	-0.67	0	-1.67	ND
UPDRS II	-0.33	1	-0.33	-0.66	-0.33	0	-4.33	0
UPDRS III	0.33	-1	-4	-0.33	2	-1.33	-4.33	1.7
II + III	0	0	-4.3	-0.99	1.67	-1.33	-8.67	1.7
NMSS	-1.33	-2	-0.5	0.66	-3.67	-1	1	0
S&E ADL	0	0	-5	6.7	0	-5	-3.33	3.33
ESS	ND	ND	ND	ND	-0.33	-0.5	1.67	-1

¹PGI-S: Patient Global Impression of Severity; CGI-S: Clinician Global Impression of Severity; PDQ-39: 39 question Parkinson’s Disease Questionnaire; MDS-UPDRS: Movement Disorder Society Universal Parkinson’s Disease Rating Scale Parts I, II, III and II+II; NMSS: Non-motor symptom score; S&E ADL: Schwab & Englund Activities of Daily Life Scale; ESS: Epworth Sleepiness Scale

In August 2023, we presented an analysis of the primary and secondary endpoints performed on these eleven participants at the Movement Disorders Society Congress. Eight participants were on active drug (three at 50 mg, two at 100 mg and three at 200 mg) and three were given placebo. The primary endpoints were safety and tolerability and no participant experienced any clinically significant adverse events. We also detailed changes in the functional assessments of motor and non-motor features using a hierarchical analysis of fifteen secondary endpoints. The study required medical professional evaluation of non-motor function, such as activities of daily living, using the MDS-UPDRS Part 2 score and evaluated motor function using the MDS-UPDRS Part 3 score. The sum of these scores is the top functional readout in the hierarchy. Clinical improvement might be concluded if the End of Study

score is lower by more than -3 to -4 points relative to the baseline score. Lowering the score (i.e. a negative change) relative to baseline or in comparison to placebo might be considered an improvement.

At the End of Study timepoint, participants administered the 200 mg dose had a combined Part 2 and Part 3 score that was lower by an average of -8.7 points. By contrast, the combined placebo score increased by an average of +1.7 points, a -10.4 point spread between actively treated versus placebo participants. Patients administered 50 or 100 mg experienced an average change of +1.7 and -1.3 points, respectively, for the combined score. An additional measure of non-motor features of disease utilized the Schwab & England Activities of Daily Life Scale (the S&E scale). The S&E scale was reduced for the 200 mg group by an average of -3.3 points relative to baseline, while the placebos had an average score increase of +3.3 points, a 6.6 point spread between the actively treated participants and the placebos; the 50 mg dose showed no effect for this measure while the 100 mg dose was on average -5.0 points lower relative to baseline. Lowering the score (i.e., a negative change) relative to baseline or in comparison to placebo might be considered a clinical improvement.

The 201 trial implements a number of novel assessments unique to us. First, we are simultaneously evaluating restoration of function in the brain and gastrointestinal tract, the first company to evaluate treatment benefit comprehensively in this patient population. We will also evaluate the ability to clear the underlying protein pathology of alpha-synuclein aggregation coincident with clinical benefit, just as we showed for the first time in our animal model studies of Risvodetinib (IkT-148009).⁸ The clearance of alpha-synuclein aggregates will be evaluated from peripheral nerves in the skin using three different skin biopsy locations on the body. We will also evaluate protein aggregate clearance from the use of so-called seed-amplification assays in the blood and spinal fluid, which may include a novel reagent developed by us that can specially monitor target-engagement using a new monoclonal antibody that recognizes the phosphorylated Tyr³⁹ form of pathological alpha-synuclein.

IkT-001Pro: Validating our prodrug technology in stable phase Chronic Myelogenous Leukemia (CML)

Market and Commercial Opportunity

IkT-001Pro is the first application of our prodrug technology that seeks to improve the oral absorption, reduce GI side effects and enhance the safety of active pharmaceutical ingredients. IkT-001Pro is a prodrug of the anti-cancer agent imatinib, an FDA approved treatment for certain blood and stomach cancers. We plan to seek approval from the FDA for IkT-001Pro in stable phase CML as an orphan indication. In 2016, imatinib became generic and up to fourteen companies have been approved to sell generic imatinib in the U.S. Sales for generic imatinib were approximately \$330 million per year across the retail counter, indicative of a potentially robust commercial market for IkT-001Pro.

In non-human primates IkT-001Pro displayed up to a 3.4-fold higher NOAEL relative to imatinib. This suggests that IkT-001Pro could reduce some side effects common to imatinib therapy for blood and stomach cancers in patients. As a consequence, we believe we have an opportunity to compete with generic imatinib sales in the U.S. market if IkT-001Pro completes clinical development and is approved by the FDA. To achieve this commercial goal, we will require implementation of an appropriate commercial strategy for prescribers, pharmacy benefit managers and payors. Primary research to validate our strategy with pharmacy benefit managers and payors suggests a commercial path exists, passing through generic imatinib. IkT-001Pro, if approved, could also compete for market share from other first line therapies for CML. One of the approved indications for Nilotinib (marketed as Tasisign[®]), for example, is for treatment of CML in patients that are imatinib intolerant. Nilotinib's label indicates it has serious cardiovascular adverse events. For those patients whose imatinib-intolerance arises from on-dosing side effects, we believe they would elect to take IkT-001Pro might be viewed as an alternative therapy if IkT-001Pro is shown to relieve those side effects in clinical trials and approved by the FDA.

Development Strategy for IkT-001Pro

CML is a proliferation of myeloid cells in the bone marrow with an incidence of 1 – 2 cases per 100,000 persons, and accounts for approximately 15% of newly-diagnosed cases of leukemia in adults. Prevalence of this disease has steadily grown over the past decade, with nearly 200,000 patients projected to be afflicted with this disease by 2050. Pathogenesis of CML is linked to a mutation in the c-Abl gene, referred to as BCR-Abl. BCR-Abl is a form of the c-Abl protein kinase that is always in the “on” state, and accounts for excessive accumulation of myeloid cells in the bone marrow and blood that is associated with leukemia. Inhibition of BCR-Abl with imatinib suppresses tumor growth. In clinical practice, imatinib is very successful at suppressing tumor growth with an 81% event-free survival rate and a 93% overall survival rate. However, 8-year follow-up studies revealed that only 55% of patients remained on therapy at 8 years, indicating that treatment failure grew over time. Treatment failures occur for a variety of reasons. We believe failure to adhere to the daily treatment regimen makes a significant contribution to treatment failure for imatinib therapy. For example, nearly 50% of patients experience nausea, diarrhea and vomiting that are not well managed. Missing more than 5 days of therapy in the first 12 months of treatment reduces the likelihood of reaching cure at the end of the fourth year of treatment by nearly 25%. Thus, while imatinib remains the medication of choice for CML, we believe that GI distress and other on-dosing side effects of imatinib therapy degrade patient adherence and lead to substantial additional medical costs, which can reach \$100,000 per patient in

the U.S. One of the key objectives for IkT-001Pro is to restore all patients to 100% treatment compliance by suppression of the GI and other on-dosing side effects for both branded and generic imatinib.

Clinical Development Strategy for IkT-001Pro in stable phase CML

As previously discussed, the ‘501’ trial evaluated the dose of IkT-001Pro equivalent to 400 mg or 600 mg imatinib mesylate. Further pre-clinical comparative studies of kT-001Pro and imatinib mesylate absorption in the gut and possibly clinical studies to evaluate doses of IkT-001Pro equivalent to as much as 800 mg imatinib mesylate are ongoing and/or planned to complete the clinical evaluation of IkT-001Pro as an alternative treatment for CML. The statutory requirements for manufacturing and quality control are being initiated as we begin to prepare an NDA package for consideration of FDA approval.

Clinical and Research Phase Programs in Other Neurological Diseases

Our RAMP™ medical chemistry program has also identified additional development opportunities for other neurological diseases which includes Multiple System Atrophy. MSA is a rare form of Parkinsonism characterized by a progressive multi-organ failure syndrome driven by the formation of alpha-synuclein aggregates in oligodendroglial cells as opposed to the formation of these aggregates in neurons as they are found in PD. MSA afflicts 15,000 to 50,000 people in the United States, is considered an orphan disease, and these patients do not respond to the anti-Parkinsonian medications frequently given to patients with PD. This dramatically simplifies the development trajectory if the MSA patients can be identified early enough to induce a clinical benefit.

In 2022, we published evidence from post-mortem analysis of the brain tissue of MSA patients that c-Abl activation is occurring in the MSA brain and that alpha-synuclein aggregates are being modified by c-Abl.⁹ We showed the same in mouse, rat and non-human primate models of MSA. In 2023, we presented data at the MDS Congress showing that in a mouse model of MSA, we could halt disease progression and suppress neurodegeneration. When we did so in the model, we substantially reduced alpha-synuclein aggregates in the affected tissue.

Our evaluation of Risvodetinib (IkT-148009) in MSA has been benefited by a grant received from the National Institute of Neurological Diseases and Stroke, an Institute of the National Institutes of Health, for \$0.39 million to fund animal model studies of Risvodetinib (IkT-148009) as a therapy for MSA. Given the outcomes of the MSA animal studies, we plan to initiate a Phase 2 study in MSA patients in up to nineteen sites in the EU, and up to six sites in the U.S. involving at least 120 patients. The proposed Phase 2 study will have primary endpoints in safety and tolerability and secondary endpoints in MSA efficacy following once daily dosing at two dose levels for 12-months. The proposed Phase 2 study will be benefited from a 10,000 patient registry of well-characterized patients that are poised for clinical trial entry. If the Phase 2 study proceeds, we currently intend to use non-dilutive capital to fund it. In 2023, we received orphan designation for Risvodetinib (IkT-148009) as a treatment for MSA.

Expertise and overall strategy

We have assembled a team of principals and advisors with deep scientific, clinical, business and leadership experience and expertise in drug development that includes neurodegenerative diseases. Our Founder and Chief Executive Officer, Milton H. Werner, Ph.D., is an internationally recognized scientist with a long history of conducting interdisciplinary research and executing on research programs in multiple therapeutic areas.

Dr. Werner is a protein biochemist and structural biologist by training, enabling him and the team of principals and advisors we have assembled to develop and characterize a portfolio of novel c-Abl inhibitors and to rapidly determine their utility in a variety of model systems for specific diseases.

Dr. Werner is joined by Terence Kelly, Ph.D., a 20-year veteran of medicinal chemistry at Boehringer-Ingelheim, and Dr. Surendra Singh who has extensive experience in process scale and commercial manufacturing of drug substances. We have engaged Clintrex Research Corporation, who is led by Karl Kieburtz, M.D. and Warren Olanow, M.D., two of the leading clinical investigators in neurodegenerative disease. Warren Olanow, MD is now the Company’s principal medical consultant. Andrew McGarry, MD (Clintrex) is our clinical trial medical monitor and our internal medical team running clinical operations, project planning and finance round out the Company’s expertise across all business disciplines. For more information regarding our management, see the section titled “Management”.

Collaborations are central components of our strategy to build and advance our pipeline of product candidates. Through NIH research grants awarded to Dr. Werner, we have subcontracted research projects in the biochemistry of neurodegeneration to Johns Hopkins University, Arizona State University, the University of Bordeaux and the Vienna (Austria) Medical University. In oncology, we have subcontracted research work in the past with the University of California, San Francisco and the CML Consortium and consult with clinicians at the Memorial Sloan-Kettering Cancer Center and the Medical College of Wisconsin. Our research endeavors have been validated by private and public granting agencies, to include the Michael J. Fox Foundation, and the National Institute of Neurological Disease and Stroke, the National Cancer Institute and the National Institute of Allergy and Infectious Disease. We believe that accessing external innovation is important to our success and we plan to remain active in accessing external innovation through business development activities and awarding of private, state and federal grants through institutions such as NIH and DoD.

Our leadership team is complemented by leading clinicians and research investigators in the areas of neurodegeneration (Drs. Ted Dawson, Valina Dawson, Ken Marek, Jay Pasricha, Jeff Kordower, Karl Kiebertz and C. Warren Olanow and Robert Hauser). We have active research collaborations with Dr. Jeffrey Kordower of Rush University and Dr. Jay Pasricha of Johns Hopkins University. Collectively, this group of collaborators and advisors represent what we believe is the cutting edge of the fields of neuroscience and neurodegeneration.

Our strategy is guided by three principles:

- **Identification and characterization of the pathway(s) governing neurodegenerative disease:** We select our therapeutic targets by identification and characterization of disease pathways that we believe drive neurodegenerative disease and elucidate the biochemistry of pathway proteins to enable small molecule targeting to treat PD and related disorders, often involving clinically validated targets.
- **Proprietary method of drug discovery in neurodegeneration:** We use our RAMP™ method to imprint the properties we desire from an approved medication onto a new molecular entity for treatment inside and outside of the brain. Using RAMP™, we believe we can establish the pharmacology profile of our product candidates using an existing medication as a template.
- **Delivering neurodegenerative treatments as a prodrug to improve pharmacology and safety:** A prodrug is a compound that, after administration, is metabolized by the body into a pharmacologically active drug. Our prodrug technology has been shown in animal models to suppress GI and other adverse events commonly associated with oral kinase inhibitors and improve drug absorption from the GI tract. We believe this technology enhances drug distribution into the target tissues, which we believe may improve safety and tolerability of our kinase inhibitors for neurodegenerative and other diseases. We must demonstrate any safety benefit using this prodrug technology in clinical trials in consultation with the FDA.

We believe that the application of these principles will significantly increase the probability of our success and will shorten the time required to bring effective therapeutics to patients with neurodegenerative and other diseases.

Drug discovery and Delivery Technologies

Engineering Small Molecule Brain Delivery

Our RAMP™ drug discovery program used imatinib as a template to design and discover a family of novel chemical entities with high potency against c-Abl, leading to Risvodetinib (IkT-148009). We showed in preclinical models that a subset of the molecules that we discovered using RAMP™ were more brain penetrant than imatinib. We believe the specific modifications in the more brain penetrant RAMP™ molecules sterically hinder engagement of transporters that could suppress accumulation of drug in the brain. Thus, we believe RAMP™ could be further applied to predicting and developing next generation molecules with enhanced brain penetration without compromise of c-Abl inhibition. As part of our ongoing research and development effort, we have increased the ability to penetrate the blood-brain barrier by as much as 5-fold in preclinical models, enabling direct treatment in the brain following oral administration.

Enhance drug absorption through a prodrug technology

In addition to the design principles, we have also deployed to develop c-Abl inhibitors capable of maintaining therapeutic concentrations in the brain, and we have also developed a delivery technology that suppresses GI side effects that occur on dosing with medications in this class. Using the anti-cancer agent imatinib as a prototype, we believe that we have shown that formation of a carbonate-linked prodrug enables absorption of the active ingredient without induction of GI side effects, resulting in an increase in the NOAEL by 3.4-fold relative to imatinib alone in non-human primates. The active ingredient we believe is more efficiently absorbed into the blood using this approach, which results in achieving therapeutic exposures with less drug administered. Since GI side effects can be common for drugs in this class and often discourage adherence to therapy, we believe this approach could be applied to any of the drugs we currently are developing for treatment of CNS disease and could be used to improve existing therapeutics in cancer as differentiated generics.

History of Business Operations and Key Events

We commenced operations in September 2008 as a Georgia limited liability company with in-licensed intellectual property relating protein kinase inhibitors to the control of bacterial and viral infectious diseases. By 2015, we had developed our own portfolio of protein kinase inhibitors to treat bacterial and viral infections, including viral infections in the brain. During 2015, we also began our endeavors in developing product candidates for other diseases of the brain, including neurodegeneration. In 2020, we completed an Initial Public Offering ("2020 IPO") and listed our Common Stock on Nasdaq under the symbol 'IKT'. Key recent operational and financing milestones are:

- In September 2018, the National Cancer Institute, an Institute of the National Institutes of Health, awarded us \$2,002,000 to advance IKT-001Pro into the clinic as a novel therapy to treat stable-phase CML.
- In September 2018, the FDA designated IKT-001Pro as an Orphan Drug for treatment of stable-phase CML.
- In February 2019, we submitted two INDs for the application of Risvodetinib (IKT-148009) in neurodegenerative disease to the FDA. One IND was for treatment of Parkinson's disease and the second IND is for the treatment of GI complications in Parkinson's patients.
- In March 2019, the FDA cleared the first IND in human study to commence in elderly healthy volunteers for Risvodetinib (IKT-148009). First dosing of patients for treatment of PD commenced on February 16, 2021. Clinical development of Risvodetinib (IKT-148009) for the GI complications in PD patients will cross-reference the first human study of Risvodetinib (IKT-148009) for the treatment of PD.
- In September 2019, the National Institute of Neurological Disease and Stroke, an Institute of the National Institutes of Health, awarded us \$3,100,838 to further advance our novel c-Abl inhibitor Risvodetinib (IKT-148009) into chronic pivotal toxicology studies for Parkinson's disease and related disorders.
- In December 2020, we completed an Initial Public Offering of 1,800,000 shares of our Common Stock for \$10.00 per share.
- In February 2021, we initiated dosing of Risvodetinib (IKT-148009) in a Phase 1 trial enrolling older and elder healthy volunteers to measure the safety, tolerability and pharmacokinetics of our drug in patients of a similar age range as Parkinson's patients.
- In April 2021, we accelerated our Phase 1 trial to initiate Multiple Ascending Dose cohorts and began the process of incorporating Parkinson's patients into these dosing cohorts.
- In June 2021, we completed a follow-on offering of 15,000,000 shares of our Common Stock for \$3.00 per share.
- In September 2021, we were awarded \$385,888 from the National Institutes of Health to evaluate our novel c-Abl inhibitor Risvodetinib (IKT-148009) in an animal model of Multiple System Atrophy.
- In May 2022, we commenced a Phase 2a trial of Risvodetinib (IKT-148009) in patients with untreated Parkinson's disease.
- In August 2022, we filed our IND application for IKT-001Pro to commence clinical development for the treatment of Stable-phase CML.
- In September 2022, we filed our IND application for the application of Risvodetinib (IKT-148009) to commence clinical development of Risvodetinib (IKT-148009) in Multiple System Atrophy ("MSA").

- In November 2022, we received a full clinical hold from the FDA on Risvodetinib (IkT-148009) programs in PD and MSA.
- In December 2022, we filed our Complete Response to the clinical hold on Risvodetinib (IkT-148009) in PD with the U.S. FDA.
- In January 2023, we received notice of the lifting of the clinical hold on Risvodetinib (IkT-148009) in PD.
- In January 2023, we completed a registered direct offering and raised gross proceeds of \$10,000,000 through the sale of our Common Stock and Common Stock equivalents and warrants.
- In March 2023, we received notice of the lifting of the clinical hold on Risvodetinib (IkT-148009) in MSA.
- In June 2023, we executed a 1-for-6 reverse split of the Company's common stock.
- In October 2023, we received Orphan Drug Designation for Risvodetinib (IkT-148009) as a treatment of MSA.
- In February 2024, we filed an At The Market (ATM) prospectus with the U. S. Securities and Exchange Commission.

Regulatory and Clinical Experiences

From September 2014 through September 2016, we conducted two non-interventional clinical studies to inform our research on the risk, development, and treatment of Progressive Multifocal Leukoencephalopathy, or PML. The results of one of the studies was published in the Journal of Neurovirology.¹¹ In 2016, the FDA permitted protocols allowing us to conduct clinical trials with the use of non-Inhibikase marketed products to treat PD. We did not conduct these studies based on our decision to pursue development of Risvodetinib (IkT-148009). In February 2021, we began our Phase 1 trial of Risvodetinib (IkT-148009) in older and elderly healthy volunteers to initiate clinical development of our lead candidate for Parkinson's and related disorders, which advanced into Phase 2 studies in 2022. In October 2022, an Investigational New Drug Application ("IND") to expand use of Risvodetinib (IkT-148009) into the Parkinson's-related disease MSA was filed with the FDA. On November 7, 2022, following review of the IND for Risvodetinib (IkT-148009) as a treatment for MSA, the FDA notified us that it was placing the Risvodetinib (IkT-148009) programs for Parkinson's disease and MSA on clinical hold. The FDA lifted the full clinical hold in January 2023 for the Parkinson's programs and in March 2023 for the MSA program.

In 2022, we commenced clinical development of IkT-001Pro, completed studies of bioequivalence to imatinib mesylate and, in 2023, discussed the parameters for approval with the FDA.

Federal Contracts and Grants

We have secured a number of grants from the United States Federal Government through the National Institutes of Health, or NIH. These grants supported most of the funding needed for our historical research and development activities. Funding through grants is nondilutive to our equity and does not need to be repaid, so long as we comply with the conditions of the grant. In connection with Federal government funding, the government retains 'march-in' rights in connection with these grants, which is a non-exclusive right to practice inventions developed from the grant funding. As we conduct our business in the future, we may expect to seek and use additional NIH funding through grant opportunities. No assurance can be given that we will obtain any grants that may be available within our areas of research and development.

Since 2009, we have received six grants from the NIH totaling \$10,053,365, to support the development of the RAMP™ drug discovery process and the application of the output of RAMP™ to therapeutic indications in neurodegenerative disease and infectious disease. Since 2017, we have received two grants from the NIH totaling \$2,286,778, to support the development of the Company's prodrug platform and oncology applications. Since 2021 we received one grant from NIH totaling \$385,888 to support our evaluation of Risvodetinib (IkT-148009) in an animal model of MSA. Under these NIH grants, we must disclose to the Federal government the research methods and outcomes of our research endeavors and patent rights and are subject to the government's march-in rights as they relate to intellectual property. As part of our reporting requirement, we must conduct independent audits of expenditures and file the outcomes of these audits with the NIH and the Department of Health and Human Services. These grants do not carry a payback provision unless there is a material breach or other transgression as it relates to use of funds. To date, we have not been found to have breached the terms of any NIH grant.

We have received one contract from the Department of Defense, or DoD, totaling \$7,129,614, to develop so-called Medical Counter Measures, or MCMs, to attempt to establish whether currently marketed inhibitors of c-Abl could act as multi-pathogen anti-infectives for bioterrorism defense. Under the terms of the DoD contract, the Company may file intellectual property related to the outcomes of the research endeavor subject to the government’s march-in rights. The expenditures incurred under this contract were subject to annual audits by the Defense Contract Audit Agency, or DCAA, and compliance with federal regulations by the Defense Contract Management Agency, or DCMA.

Material Agreements

Sphaera Pharma Pte. Ltd.

On March 2, 2012, we entered into a collaborative research and development agreement, or the Sphaera Agreement, with Sphaera Pharma Pte. Ltd., or Sphaera, to collaborate on the development of the prodrug technology to be applied to protein kinase inhibitors for oncology and non-oncology indications. Under the terms of the Sphaera Agreement, each party would retain its preexisting intellectual property, but any intellectual property conceived or reduced to practice under and certain results arising from the Sphaera Agreement would be assigned to us. On October 5, 2012, we and Sphaera amended the Sphaera Agreement to reflect joint patent applications in the U.S. and India by us and Sphaera for a series of novel compounds. While the underlying intellectual property would be jointly owned, we have the exclusive right to commercialize thirteen of the twenty-four linkers detailed in the filed patent applications, collectively, the Company Compounds, including the linker attached to imatinib that comprises IkT-001Pro with the remaining nine linkers owned by Sphaera, collectively, the Sphaera Compounds. Sphaera has the right to develop the Company Compounds for oncology indications but may not commercialize the Company Compounds unless we abandon the Company Compounds. We have notified Sphaera that we do not intend to abandon the Company Compounds. We do not currently have the right to develop the Sphaera Compounds. Additionally, if either party files an IND for a Company Compound that has been abandoned by the other party for an oncology indication in humans, the non-filing party is prohibited from developing such Company Compound. In 2023, Sphaera liquidated and transferred its interests to Pivot Holding LLC, a U.S. entity.

The prosecution of patents related to the Company Compounds, which includes the prodrug technology, is the responsibility of the Company.

As consideration for its services, Sphaera has received a fixed fee of \$160,000 and may be entitled to certain milestone payments, none of which have yet to have been reached, and single-digit royalty payments of a percentage of annual net sales and sublicenses were a compound covered by this agreement ever commercialized:

Milestone Event	Payment
First dosing of patients in US Phase 1 trial	\$ 250,000
US Phase 1 trial completion with endpoints met	500,000
US Phase 2 trial completion with endpoints met	875,000
FDA Approval	4,000,000
Total potential milestone payments	<u>\$5,625,000</u>

Other Agreements

Consulting Agreements

Our non-employee Directors, non-employee management and non-employee technical staff have signed multi- year consulting agreements that provide for protections of intellectual property, trade secrets and ensure consistent commitment to Company research and development activities. These agreements provide a scope of work, reimbursement for incurred costs of travel and equity compensation.

Clinical Research Organization Agreements

We work with several clinical research organizations for execution of clinical trials includes medical, analytical and pharmacy support services along with clinical research management and data handling according to a statistical analysis plan. Our clinical development team is formed, in part, by two physicians and a clinical research manager employed by Clintrex Research Corporation and under contract to us, who have specialized expertise in clinical trial development and execution for Parkinson's Disease research.

cGMP Manufacturing

Our chemical manufacturing organization is STA Pharmaceutical US LLC, a subsidiary of WuXi AppTec Co., Ltd., which is based in China and provides process scale development and production of active pharmaceutical ingredients. Formulation and finishing services are provided through contracts on an as-needed basis, including current Good Manufacturing Practice or cGMP manufacturing of active pharmaceutical ingredients.

Sponsored Research Agreements

We regularly enter into agreements with academic and research institutions under which the institution agrees to perform certain testing and research for us in exchange for incremental fee payments, or the Sponsored Research Agreements. These Agreements allow us to explore the potential utility of our compounds for therapeutic indications we wish to pursue. We have previously entered into Sponsored Research Agreements with Johns Hopkins, University of Massachusetts Medical School — Worcester Campus and Louisiana State University, Shreveport, and Arizona State University, collectively the Institutions. The scope of work of these Sponsored Research Agreements is derived from the associated grants, in which the sponsored project is a subcontract to the main grant in which the Company is the primary party and Dr. Werner is the principal investigator. Incremental fee payments are due to the Institutions on a monthly or quarterly basis, and certain payments depend on the completion by the Institutions of testing and research milestones. The Sponsored Research Agreements contain estimated completion dates which may be extended by written agreement of the parties. Each Sponsored Research Agreement may be terminated by either party on 30 days written notice, and upon termination we must reimburse the applicable Institution for all costs and reasonably incurred financial commitments, regardless of which party initiates the termination. Under the Sponsored Research Agreements, we retain all rights, title and interest in any information designated as purchaser property, as defined in the Sponsored Research Agreements. We own exclusively, and retain all right, title and interest in and to, our property provided as part of any Sponsored Research Agreement. Any and all of our property remains our sole property and will be used by an Institution solely in performing the research contemplated in the Sponsored Research Agreement. The relevant Institution retains all right, title and interest in and to its inventions, discoveries, material and improvements, that were in existence prior to execution of a Sponsored Research Agreement. The relevant Institution does not acquire rights in our compounds as a result of sponsored research. We are not required to license any rights related to our compounds as a result of sponsored research and we own the results of sponsored research without restriction on their use.

Manufacturing

We believe it is important to our business and success to have a reliable, high-quality preclinical and clinical drug supply.

We do not currently own or operate facilities for product manufacturing, storage, distribution or testing.

We rely on third-party contract manufacturers, or CMOs, to manufacture and supply our preclinical and clinical materials to be used during the development of our product candidates. We have established relationships with several CMOs, including AgNo Pharmaceuticals, LLC and PepTech Corporation, both in China, and we have contracted for cGMP manufacturing in the United States with STA Pharmaceutical US LLC and STA Pharmaceuticals Co., Ltd., both subsidiaries of WuXi AppTec Co., Ltd., which is based in China. We have contracted solid dosage formulations of Risvodeltinib (IkT-148009) and IkT-001Pro with STA Pharmaceuticals, Ltd. in China and with Emerson Pace Laboratories in the United States, respectively.

We do not currently need commercial manufacturing capacity. When and if this becomes relevant, we intend to evaluate both third-party manufacturers as well as building out internal capabilities and capacity. We may choose one or both options, or a combination of the two.

Commercialization Plan

We do not currently have any approved drugs and we do not expect to have any approved drugs in the near term. Therefore, we have no sales, marketing or commercial product distribution capabilities and have no experience as a company in marketing drugs. However, members of our board of directors have commercial experience and we have conducted a full commercial opportunity assessment for our lead product for PD in the U.S. market. We may develop one or all of our products and commercialize them ourselves, or we may license or form partnerships with other companies for commercialization of our products in the future.

Competition

The pharmaceutical industries, including in the neurodegenerative disease field, are characterized by rapidly advancing technologies, strong competition and an emphasis on intellectual property. We face substantial competition from many different sources, including large and specialty pharmaceutical companies, academic research institutions, governmental agencies and public and private research institutions. We believe that the key competitive factors affecting the success of any of our product candidates will include efficacy, safety profile, method of administration, cost, level of promotional activity and intellectual property protection.

Our product candidates for treatment of neurodegenerative diseases will compete with approved treatments as well as other therapies that may be in clinical or preclinical development or that have yet to be discovered. Historically, approved treatments for PD and related neurodegenerative disorders treat the symptoms of such diseases rather than halting or slowing the progression of the disease. We are not in the business of treating symptoms of disease. We intend to halt or slow the progression of the disease, which is known as disease modification and our product candidates are intended to modify disease. We believe that our product candidates, if approved by regulatory agencies in the U.S. and abroad, will compete with other potential therapies intended to halt or slow the progression of neurodegenerative disease that are being developed by a number of companies and institutions. Companies developing therapeutics in the neurodegenerative disease area include large companies with significant financial resources, such as Biogen, Inc., Neupore Therapies, Inc., Bristol Meyers Squibb, Roche Holdings AG, Prothena Corporation plc, Sanofi S.A., Takeda Pharmaceutical Co. Ltd., UCB, S.A., Denali Therapeutics Inc., Sun SPARC, 1st Biotherapeutics and AbbVie Inc. Denali Therapeutics Inc. and Eli Lilly and Company are pursuing treatments for specific genetic defects that could prevent onset of disease or affect progression in Parkinson's patients. In addition, a number of companies have developed c-Abl inhibitors for oncology and any one of them could be in possession of an inhibitor that could be used for clinical development for neurodegenerative diseases. These include Novartis AG, Bristol-Meyers Squibb Company, Boehringer-Ingelheim GmbH and GlaxoSmithKline plc. Two companies, Sun Pharma Advanced Research Company Ltd. (SPARC) and 1st Biotherapeutics, Inc., have initiated clinical studies with proprietary c-Abl inhibitors for PD using molecules initially developed for treatment of blood cancer(s). In addition, we believe Botox[®] coupled with physical therapy is being explored in physician-led trials for neurogenic constipation, but we are not aware of any formal development programs by other companies.

Intellectual Property

The proprietary nature of, and protection for, our product candidates, processes, and know-how are important to our business. Our success depends in part on our ability to protect the proprietary nature of our product candidates, processes and know-how, to operate without infringing on the proprietary rights of others and to prevent others from infringing our proprietary rights. We seek and maintain patent protection in the United States and internationally for our product candidates and other technology. We endeavor to patent or in-license technology, inventions and improvements that we consider important to the development of our business. In addition to patent protection, we intend to use other means to protect our proprietary rights, including pursuing terms of marketing or data exclusivity, orphan drug status (if applicable), and similar rights that are available under regulatory provisions in certain territories, including the United States, Europe and Japan. We also rely on trade secrets, know-how and continuing innovation to develop and maintain our competitive position.

For our product candidates, we generally pursue patent protection covering compositions of matter and methods of use. However, given that the development of our technology and product candidates is at an early stage, our intellectual property portfolio with respect to certain aspects of our technology and product candidates is also at an early stage. As further described below, we have filed or intend to file patent applications on various product candidates for composition of matter and other aspects of our technology and product candidates, and as we continue the development of our product candidates, we intend to identify additional means of obtaining patent protection that would potentially enhance commercial success, including protection for additional methods of use, formulation or manufacture.

We cannot be certain that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed by us in the future, nor can we be sure that any of our existing patents or any patents granted to us in the future will be commercially useful in protecting our technology. Any of our intellectual property and proprietary rights could be challenged, invalidated, circumvented, infringed or misappropriated, or such intellectual property and proprietary rights may not be sufficient to permit us to take advantage of current market trends or otherwise to provide competitive advantages. For more information, please see "Risk Factors — Risks Relating to Intellectual Property."

The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In most countries in which we file, the patent term is 20 years from the earliest date of filing a non-provisional patent application. The patent expirations reported below assume the patent is not rendered invalid or unenforceable by legal action and that all required fees are timely paid. In the United States, a patent may be entitled to Patent Term Adjustment for Patent Office delay. Where known, this has been included in the expiration dates described below. Further, in the United States, the patent term of a single patent that covers an

FDA-approved drug may also be eligible for patent term extension, which permits patent term restoration as compensation for the patent term lost during the FDA regulatory review process. The Hatch-Waxman Act permits a patent term extension of up to five years beyond the expiration of the patent. The length of the patent term extension is related to the length of time the drug is under regulatory review. Patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent applicable to an approved drug may be extended and the extension can only be obtained for patents covering the approved drug, a method for using it, or a method for manufacturing it. Similar provisions are available in Europe and certain other foreign jurisdictions to extend the term of a patent that covers an approved drug. In the future, if and when our eligible products receive FDA approval, we expect to apply for patent term extensions on patents covering those products. We plan to seek patent term extensions to any of our issued patents in any jurisdiction where these are available; however, there is no guarantee that the applicable authorities, including the FDA in the United States, will agree with our assessment of whether such extensions should be granted, and if granted, the length of such extensions.

All of our novel compounds were funded in whole or in part by the U.S. government and are therefore subject to federal march-in rights. When new technologies are developed with U.S. government funding, the U.S. government generally obtains certain rights in any resulting patents, including a non-exclusive license authorizing the U.S. government to use the invention or to have others use the invention on its behalf, commonly referred to as march-in rights. For more information regarding the risks related to our intellectual property, see “Risk Factors — Risks Related to Our Intellectual Property.”

As of the date of this Report, our patent portfolio included: (i) nine issued patents and two pending patent applications in the United States and (ii) eleven issued foreign patents and four pending foreign patent applications. Patents issuing from the applications in this portfolio, if granted, will expire between 2033 and 2037, not taking into account any potential patent-term adjustments or extensions that may be available in the future.

One family of patents and applications covers compositions of matter for IkT-001Pro and related chemical compounds, as well as methods of using those compositions. This family includes two issued U.S. patents: U.S. Patent No. 9,487,500, which claims a genus of compounds including IkT-001Pro, and U.S. Patent No. 9,907,796, which claims methods of using a genus of compounds, including IkT-001Pro, to treat certain tumoral disease and certain infectious diseases. These U.S. Patents will expire between 2033 and 2034, not including any potential patent term extensions. This family does not include any pending patent applications in the U.S. Outside the U.S., this family includes issued patents in Europe, Japan, and Australia, and a pending patent application in Canada. Outside the U.S., patents issuing from the applications in this family, if granted, will expire in 2033, not taking into account any potential patent term adjustments or extensions that may be available in the future. This family of patents and applications is jointly owned by us and Sphaera. Under the terms of our agreement with Sphaera, described above under “— Material Agreements — Sphaera Pharma Pte. Ltd.” we have the exclusive right to commercialize certain compounds disclosed in these applications, including IkT-001Pro, for cancer treatments.

Two families of patents and applications cover compositions of matter for IkT-148009 and IkT-01427, the IkT-148x portfolio, and methods of use relating to those compositions. Patents issuing from the applications in these families, if granted, will expire between 2036 and 2037, not taking into account any potential patent-term adjustments or extensions that may be available in the future. These families include seven issued U.S. patents and two pending U.S. patent applications. The issued U.S. patents, U.S. Patent No. 9,828,370, U.S. Patent No. 10,118,923, U.S. Patent No. 10,316,031, U.S. Patent No. 10,344,027, U.S. Patent No. 10,906,896, U.S. Patent no. 11,407,747, and U.S. Patent no. 11,725,005, will expire in 2036, not including any potential patent term extensions, and include claims that cover compositions of matter for IkT-148009 and IkT-01427, as well as claims that cover methods of using those compositions to treat certain cancers and certain infectious diseases. Outside the U.S., these families include issued patents in Japan, Australia, and Canada, and pending patent applications in Japan, Canada, and Europe. These families are solely owned by us.

In addition to patent protection, we also rely on trade secrets, know how, other proprietary information and continuing technological innovation to develop and maintain our competitive position. We seek to protect and maintain the confidentiality of proprietary information to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection. Although we take steps to protect our proprietary information and trade secrets, including through contractual means with our employees and consultants, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology. Thus, we may not be able to meaningfully protect our trade secrets. It is our policy to require our employees, directors, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us or serving as a member of our board of directors. These agreements provide that all confidential information concerning our business or financial affairs developed or made known to the individual during the course of the individual’s relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. Our agreements with employees also provide that all inventions conceived by the employee in the course of employment with us or from the employee’s use of our confidential information are our exclusive property. However, such confidentiality agreements and invention assignment agreements can be breached and we may not have adequate remedies for any such breach. For more information regarding the risks related to our intellectual property, see “Risk Factors — Risks Related to Our Intellectual Property.”

The patent positions of pharmaceutical companies like ours are generally uncertain and involve complex legal, scientific and factual questions. Our commercial success will also depend in part on not infringing upon the proprietary rights of third parties. It is uncertain whether the issuance of any third-party patent would require us to alter our development or commercial strategies, or our drugs or processes, obtain licenses or cease certain activities. Our breach of any license agreements or our failure to obtain a license to proprietary rights required to develop or commercialize our future products may have a material adverse impact on us. If third parties prepare and file patent applications in the United States that also claim technology to which we have rights, we may have to participate in interference or derivation proceedings in the United States Patent and Trademark Office (the “USPTO”) to determine priority of invention. For more information, see “Risk Factors — Risks Related to Our Intellectual Property.”

Government Regulation

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act, or FDCA, and its implementing regulations. The process of obtaining regulatory approvals and the subsequent compliance with applicable federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject an applicant to a variety of administrative or judicial sanctions, such as the FDA’s refusal to approve pending NDAs, withdrawal of an approval, imposition of a clinical hold, issuance of warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties.

The process required by the FDA before a drug may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests, animal studies and formulation studies in compliance with the FDA’s good laboratory practice regulations;
- submission to the FDA of an IND, which must become effective before human clinical trials may begin;
- approval by an independent IRB at each clinical site before each trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with cGCPs requirements to establish the safety and efficacy of the proposed drug product for each indication;
- submission to the FDA of an NDA;
- satisfactory completion of an FDA advisory committee review, if applicable;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the product is produced to assess compliance with current good manufacturing practice requirements and to assure that the facilities, methods and controls are adequate to preserve the drug’s identity, strength, quality and purity;
- satisfactory completion of FDA audits of clinical trial sites to assure compliance with cGCPs and the integrity of the clinical data;
- payment of user fees and securing FDA approval of the NDA; and
- compliance with any post-approval requirements, including the potential requirement to implement a REMS, and the potential requirement to conduct post-approval studies.

Preclinical Studies

Preclinical studies include laboratory evaluation of product chemistry, toxicity and formulation, as well as animal studies to assess potential safety and efficacy. An IND sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data and any available clinical data or literature, among other things, to the FDA as part of an IND. Some preclinical testing may continue even after the IND is submitted. An IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to one or more proposed clinical trials and places the clinical trial on a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. As a result, submission of an IND may not result in the FDA allowing clinical trials to initiate.

Clinical Trials

Clinical trials involve the administration of the investigational new drug to human subjects under the supervision of qualified investigators in accordance with cGCP requirements, which include the requirement that all research subjects provide their informed consent in writing for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA. In addition, an IRB at each institution participating in the clinical trial must review and approve the plan for any clinical trial before it initiates at that institution. Information about certain clinical trials must be submitted within specific time frames to the National Institutes of Health, or NIH, for public dissemination on their www.clinicaltrials.gov website.

Human clinical trials are typically conducted in three sequential phases, which may overlap or be combined:

- Phase 1: The drug is initially introduced into healthy human subjects or patients with the target disease or condition and tested for safety, dosage tolerance, absorption, metabolism, distribution, excretion and, if possible, to gain an early indication of its effectiveness.
- Phase 2: The drug is administered to a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage.
- Phase 3: The drug is administered to an expanded patient population, generally at geographically dispersed clinical trial sites, in well-controlled clinical trials to generate enough data to statistically evaluate the efficacy and safety of the product for approval, to establish the overall risk-benefit profile of the product, and to provide adequate information for the labeling of the product.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and more frequently if serious adverse events occur. Phase 1, Phase 2 and Phase 3 trials may not be completed successfully within any specified period, or at all. Furthermore, the FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients.

Marketing Approval

Assuming successful completion of the required clinical testing, the results of the preclinical and clinical studies, together with detailed information relating to the product's chemistry, manufacture, controls and proposed labeling, among other things, are submitted to the FDA as part of an NDA requesting approval to market the product for one or more indications. In most cases, the submission of an NDA is subject to a substantial application user fee. Under the Prescription Drug User Fee Act, or PDUFA, guidelines that are currently in effect, the FDA has a goal of ten months from the date of "filing" of a standard NDA, for a new molecular entity, to review and act on the submission. This review typically takes twelve months from the date the NDA is submitted to the FDA because the FDA has approximately two months to make a "filing" decision.

The FDA also may require submission of a Risk Evaluation and Mitigation Strategy (REMS) plan to ensure that the benefits of the drug outweigh its risks. The REMS plan could include medication guides, physician communication plans, assessment plans, and/or elements to assure safe use, such as restricted distribution methods, patient registries, or other risk minimization tools.

The FDA conducts a preliminary review of all NDAs within the first 60 days after submission, before accepting them for filing, to determine whether they are sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. The FDA reviews an NDA to determine, among other things, whether the drug is safe and effective and whether the facility in which it is manufactured, processed, packaged or held meets standards designed to assure the product's continued safety, quality and purity.

The FDA may refer an application for a novel drug to an advisory committee. An advisory committee is a panel of independent experts, including clinicians and other scientific experts, which reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving an NDA, the FDA typically will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA may inspect one or more clinical trial sites to assure compliance with cGCP requirements.

After evaluating the NDA and all related information, including the advisory committee recommendation, if any, and inspection reports regarding the manufacturing facilities and clinical trial sites, the FDA may issue an approval letter, or, in some cases, a complete response letter. A complete response letter generally contains a statement of specific conditions that must be met in order to secure final approval of the NDA and may require additional clinical or preclinical testing in order for the FDA to reconsider the application. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. If and when those conditions have been met to the FDA's satisfaction, the FDA will typically issue an approval letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications.

Even if the FDA approves a product, it may limit the approved indications for use of the product, require that contraindications, warnings or precautions be included in the product labeling, require that post-approval studies, including Phase 4 clinical trials, be conducted to further assess a drug's safety after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution and use restrictions or other risk management mechanisms under a REMS, which can materially affect the potential market and profitability of the product. The FDA may prevent or limit further marketing of a product based on the results of post-marketing studies or surveillance programs. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes, and additional labeling claims, are subject to further testing requirements and FDA review and approval.

Special FDA Expedited Review and Approval Programs

The FDA has various programs, including fast track designation, accelerated approval, priority review, and breakthrough therapy designation, which are intended to expedite or simplify the process for the development and FDA review of drugs that are intended for the treatment of serious or life-threatening diseases or conditions and demonstrate the potential to address unmet medical needs. The purpose of these programs is to provide important new drugs to patients earlier than under standard FDA review procedures.

To be eligible for a fast track designation, the FDA must determine, based on the request of a sponsor, that a product is intended to treat a serious or life-threatening disease or condition and demonstrates the potential to address an unmet medical need. The FDA will determine that a product will fill an unmet medical need if it will provide a therapy where none exists or provide a therapy that may be potentially superior to existing therapy based on efficacy or safety factors. The FDA may review sections of the NDA for a fast track product on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA, the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA.

The FDA may give a priority review designation to drugs that offer major advances in treatment, or provide a treatment where no adequate therapy exists. A priority review means that the goal for the FDA to review an application is six months, rather than the standard review of ten months under current PDUFA guidelines. Under the new PDUFA agreement, these six and ten month review periods are measured from the "filing" date rather than the receipt date for NDAs for new molecular entities, which typically adds approximately two months to the timeline for review and decision from the date of submission. Most products that are eligible for fast track designation are also likely to be considered appropriate to receive a priority review.

In addition, products tested for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may be eligible for accelerated approval and may be approved on the basis of adequate and well-controlled clinical trials establishing that the drug product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, or IMM, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA may require a sponsor of a drug receiving accelerated approval to perform post-marketing studies to verify and describe the predicted effect on IMM or other clinical endpoint, and the drug may be subject to accelerated withdrawal procedures.

Moreover, under the provisions of the Food and Drug Administration Safety and Innovation Act, or FDASIA, passed in July 2012, a sponsor can request designation of a product candidate as a “breakthrough therapy.” A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Drugs designated as breakthrough therapies are also eligible for accelerated approval. The FDA must take certain actions, such as holding timely meetings and providing advice, intended to expedite the development and review of an application for approval of a breakthrough therapy.

Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. We may explore some of these opportunities for our product candidates as appropriate.

Accelerated Approval Pathway

The FDA may grant accelerated approval to a drug for a serious or life-threatening condition that provides meaningful therapeutic advantage to patients over existing treatments based upon a determination that the drug has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. The FDA may also grant accelerated approval for such a condition when the product has an effect on an intermediate clinical endpoint that can be measured earlier than an effect on IMM, and that is reasonably likely to predict an effect on IMM or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments. Drugs granted accelerated approval must meet the same statutory standards for safety and effectiveness as those granted traditional approval.

For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. An intermediate clinical endpoint is a measurement of a therapeutic effect that is considered reasonably likely to predict the clinical benefit of a drug, such as an effect on IMM. The FDA has limited experience with accelerated approvals based on intermediate clinical endpoints, but has indicated that such endpoints generally may support accelerated approval where the therapeutic effect measured by the endpoint is not itself a clinical benefit and basis for traditional approval, if there is a basis for concluding that the therapeutic effect is reasonably likely to predict the ultimate clinical benefit of a drug.

The accelerated approval pathway is most often used in settings in which the course of a disease is long and an extended period of time is required to measure the intended clinical benefit of a drug, even if the effect on the surrogate or intermediate clinical endpoint occurs rapidly. Thus, accelerated approval has been used extensively in the development and approval of drugs for treatment of a variety of cancers in which the goal of therapy is generally to improve survival or decrease morbidity and the duration of the typical disease course requires lengthy and sometimes large trials to demonstrate a clinical or survival benefit.

The accelerated approval pathway is usually contingent on a sponsor’s agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the drug’s clinical benefit. As a result, a drug candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or confirm a clinical benefit during post-marketing studies, would allow the FDA to withdraw the drug from the market on an expedited basis. All promotional materials for drug candidates approved under accelerated regulations are subject to prior review by the FDA. In particular, the Food and Drug Omnibus Reform Act, or “FDORA” enacted in the Consolidated Appropriations Act on December 29, 2022, further directs FDA to specify conditions for post-approval studies for products approved under accelerated approval that may provide additional requirements and timelines for conducting such studies. FDORA also directs FDA to develop procedures for withdrawing a product’s accelerated approval on an expedited basis, which may also impact one or more of our products, if we are no longer able to continue to meet the requirements for accelerated approval.

505(b)(2) Pathway

The 505(b)(2) new drug application (NDA) is an FDA abbreviated drug approval pathway. The pathway was created by the Hatch-Waxman Amendments of 1984, with 505(b)(2) referring to a section of the FDCA. The provisions of 505(b)(2) were created, in part, to help avoid unnecessary duplication of studies already performed on a previously approved (“reference” or “listed”) drug; the section gives the FDA express permission to rely on data not developed by the NDA applicant and for which the applicant has not obtained a right of reference. A 505(b)(2) NDA contains full safety and effectiveness reports but allows at least some of the information required for NDA approval, such as safety and efficacy information on the active ingredient, to come from studies not conducted by or for the applicant. The FDA may also require the applicant to perform additional studies or measurements to support the change from the approved product. The FDA may then approve the new product candidate for all or some of the label indications for which the referenced product has been approved, as well as for any indication sought by the Section 505(b)(2) applicant.

Orphan Drug Designation and Exclusivity

Under the Orphan Drug Act, the FDA may designate a drug product as an “orphan drug” if it is intended to treat a rare disease or condition (generally meaning that such disease or condition affects fewer than 200,000 individuals in the United States, or more in cases in which there is no reasonable expectation that the cost of developing and making a drug product available in the United States for treatment of the disease or condition will be recovered from sales of the product). A company must request orphan product designation before submitting an NDA. If the request is granted, the FDA will disclose the identity of the therapeutic agent and its potential use. Orphan product designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If a product with orphan status receives the first FDA approval for the disease or condition for which it has such designation or for a select indication or use within the rare disease or condition for which it was designated, the product generally will be receiving orphan product exclusivity. Orphan product exclusivity means that the FDA may not approve any other applications for the same product for the same indication for seven years, except in certain limited circumstances. If a drug or drug product designated as an orphan product ultimately receives marketing approval for an indication broader than what was designated in its orphan product application, it may not be entitled to exclusivity. Orphan exclusivity will not bar approval of another product under certain circumstances, including if a subsequent product with the same active ingredient for the same indication is shown to be clinically superior to the approved product on the basis of greater efficacy or safety, or providing a major contribution to patient care, or if the company with orphan drug exclusivity is not able to meet market demand. Further, the FDA may approve more than one product for the same orphan indication or disease as long as the products contain different active ingredients. Moreover, competitors may receive approval of different products for the indication for which the orphan product has exclusivity or obtain approval for the same product but for a different indication for which the orphan product has exclusivity.

Post-Approval Requirements

Drugs manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to record keeping, periodic reporting, product sampling and distribution, advertising and promotion and reporting of adverse experiences with the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims are subject to prior FDA review and approval. There are continuing, annual user fee requirements for any marketed products and the establishments where such products are manufactured, as well as new application fees for supplemental applications with clinical data.

The FDA may impose a number of post-approval requirements as a condition of approval of an NDA. For example, the FDA may require post-marketing testing, including Phase 4 clinical trials, and surveillance to further assess and monitor the product’s safety and effectiveness after commercialization.

In addition, drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and state agencies, and are subject to periodic unannounced inspections by the FDA and these state agencies for compliance with cGMP requirements. Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP requirements and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance.

Once an approval of a drug or medical device is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in mandatory revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending NDAs or supplements to approved NDAs, or suspension or revocation of product approvals;

- product seizure or detention, or refusal to permit the import or export of products; and
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Drugs or devices may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

U.S. Healthcare Fraud and Abuse Laws and Compliance Requirements

We are subject to various federal and state laws targeting fraud and abuse in the healthcare industry. These laws may impact, among other things, our proposed sales and marketing programs. In addition, we may be subject to patient privacy regulation by both the federal government and the states in which we conduct our business. The laws that may affect our operations include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from soliciting, receiving, offering or paying remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs. The term “remuneration” has been broadly interpreted to include anything of value;
- federal false claims and civil monetary penalties laws, including the federal civil False Claims Act, which prohibits anyone from, among other things, knowingly presenting, or causing to be presented, for payment to federal programs (including Medicare and Medicaid) claims for items or services that are false or fraudulent;
- provisions of HIPAA, which created federal criminal statutes that prohibit, among other things, knowingly and willfully executing a scheme to defraud any healthcare benefit program or making false statements in connection with the delivery of or payment for healthcare benefits, items or services. In addition, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations, impose certain requirements relating to the privacy, security and transmission of individually identifiable health information; and
- the federal Physician Payments Sunshine Act requirements, under the Patient Protection and Affordable Care Act, which require manufacturers of certain drugs and biologics to track and report to Centers for Medicare & Medicaid Services, or CMS, payments and other transfers of value they make to U.S. physicians and teaching hospitals as well as physician ownership and investment interests in the manufacturer.

Regulation Outside the United States

To the extent that any of our product candidates, once approved, are sold in a foreign country, we may be subject to similar foreign laws and regulations, which may include, for instance, applicable post-marketing requirements, including safety surveillance, anti-fraud and abuse laws and implementation of corporate compliance programs and reporting of payments or other transfers of value to healthcare professionals.

To market our future products in the European Economic Area, or EEA (comprised of the 28 member states of the EU plus Norway, Iceland and Liechtenstein), and many other foreign jurisdictions, we must obtain separate regulatory approvals. More concretely, in the EEA, medicinal products can only be commercialized after obtaining a Marketing Authorization, or MA. There are two types of marketing authorizations:

- The Community MA, which is issued by the European Commission through the Centralized Procedure, based on the opinion of the Committee for Medicinal Products for Human Use of the EMA and which is valid throughout the entire territory of the EEA. The Centralized Procedure is mandatory for certain types of products, such as biotechnology medicinal products, orphan medicinal products and medicinal products indicated for the treatment of AIDS, cancer, neurodegenerative disorders, diabetes, autoimmune and viral diseases. The Centralized Procedure is optional for products containing a new active substance not yet authorized in the EEA, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the EU; and
- National MAs, which are issued by the competent authorities of the Member States of the EEA and only cover their respective territory, are available for products not falling within the mandatory scope of the Centralized Procedure. Where a product has already been authorized for marketing in a Member State of the EEA, this National MA can be recognized in another Member State through the Mutual Recognition Procedure. If the product has not received a National MA in any Member State at the time of application, it can be approved simultaneously in various Member States through the Decentralized Procedure.

Under the above-described procedures, before granting the MA, the EMA or the competent authorities of the Member States of the EEA assess the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy.

Data and Marketing Exclusivity

In the EEA, new products authorized for marketing, or reference products, qualify for eight years of data exclusivity and an additional two years of market exclusivity upon marketing authorization. The data exclusivity period prevents generic or biosimilar applicants from relying on the preclinical and clinical trial data contained in the dossier of the reference product when applying for a generic or biosimilar marketing authorization in the EU during a period of eight years from the date on which the reference product was first authorized in the EU. The market exclusivity period prevents a successful generic or biosimilar applicant from commercializing its product in the EU until 10 years have elapsed from the initial authorization of the reference product in the EU. The 10-year market exclusivity period can be extended to a maximum of eleven years if, during the first eight years of those 10 years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies.

Orphan Drug Designation

In the EEA, a medicinal product can be designated as an orphan drug if its sponsor can establish that the product is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition affecting not more than five in ten thousand persons in the EU when the application is made, or that the product is intended for the diagnosis, prevention or treatment of a life-threatening, seriously debilitating or serious and chronic condition in the EU and that without incentives it is unlikely that the marketing of the drug in the EU would generate sufficient return to justify the necessary investment in development. For either of these conditions, the applicant must demonstrate that there exists no satisfactory method of diagnosis, prevention or treatment of the condition in question that has been authorized in the EU or, if such method exists, the drug will be of significant benefit to those affected by that condition.

In the EEA, an application for designation as an orphan product can be made any time prior to the filing of an application for approval to market the product. Marketing authorization for an orphan drug leads to a 10-year period of market exclusivity. During this market exclusivity period, the EMA or the member state competent authorities, cannot accept another application for a marketing authorization, or grant a marketing authorization, for a similar medicinal product for the same indication. The period of market exclusivity is extended by two years for medicines that have also complied with an agreed pediatric investigational plan.

This period may, however, be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan drug designation, for example because the product is sufficiently profitable not to justify market exclusivity. Market exclusivity can be revoked only in very selected cases, such as consent from the marketing authorization holder, inability to supply sufficient quantities of the product, demonstration of “clinical superiority” by a similar medicinal product, or, after a review by the Committee for Orphan Medicinal Products, requested by a member state in the fifth year of the marketing exclusivity period (if the designation criteria are believed to no longer apply). Medicinal products designated as orphan drugs are eligible for incentives made available by the EU and its Member States to support research into, and the development and availability of, orphan drugs.

Other U.S. Regulatory Matters

Manufacturing, sales, promotion and other activities following product approval are also subject to regulation by numerous regulatory authorities in the United States in addition to the FDA, including the Centers for Medicare & Medicaid Services, other divisions of the Department of Health and Human Services, the Department of Justice, the Drug Enforcement Administration, the Consumer Product Safety Commission, the Federal Trade Commission, the Occupational Safety & Health Administration, the Environmental Protection Agency and state and local governments.

For example, in the United States, sales, marketing and scientific and educational programs also must comply with state and federal fraud and abuse laws. These laws include the federal Anti-Kickback Statute, which makes it illegal for any person, including a prescription drug manufacturer (or a party acting on its behalf), to knowingly and willfully solicit, receive, offer or pay any remuneration that is intended to induce or reward referrals, including the purchase, recommendation, order or prescription of a particular drug, for which payment may be made under a federal healthcare program, such as Medicare or Medicaid. Violations of this law are punishable by up to five years in prison, criminal fines, administrative civil money penalties and exclusion from participation in federal healthcare programs. Moreover, the ACA provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act.

Pricing and rebate programs must comply with the Medicaid rebate requirements of the U.S. Omnibus Budget Reconciliation Act of 1990 and more recent requirements in the ACA. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. Products must meet applicable child-resistant packaging requirements under the U.S. Poison Prevention Packaging Act. Manufacturing, sales, promotion and other activities also are potentially subject to federal and state consumer protection and unfair competition laws.

The distribution of pharmaceutical products is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products.

The failure to comply with any of these laws or regulatory requirements subjects firms to possible legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can result in criminal prosecution, fines or other penalties, injunctions, requests for recall, seizure of products, total or partial suspension of production, denial or withdrawal of product approvals or refusal to allow a firm to enter into supply contracts, including government contracts. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. Prohibitions or restrictions on sales or withdrawal of future products marketed by us could materially affect our business in an adverse way.

Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements; (ii) additions or modifications to product labeling; (iii) the recall or discontinuation of our products; or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business.

U.S. Patent-Term Restoration and Marketing Exclusivity

Depending upon the timing, duration and specifics of FDA approval of any future product candidates, some of our U.S. patents may be eligible for limited patent term extension under the Hatch-Waxman Act. The Hatch- Waxman Act permits restoration of the patent term of up to five years as compensation for patent term lost during product development and FDA regulatory review process. Patent-term restoration, however, cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent-term restoration period is generally half the time between the effective date of an IND and the submission date of an NDA or BLA plus the time between the submission date of an NDA or BLA and the approval of that application, except that the review period is reduced by any time during which the applicant failed to exercise due diligence. Only one patent applicable to an approved drug is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The USPTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we may apply for restoration of patent term for our currently owned or licensed patents to add patent life beyond its current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant NDA or BLA.

Market exclusivity provisions under the FDCA also can delay the submission or the approval of certain applications. The FDCA provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to gain approval of an NDA for a new molecular entity. A drug is a new molecular entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an ANDA or a 505(b)(2) NDA submitted by another company for another version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement. The FDCA also provides three years of marketing exclusivity for an NDA, 505(b)(2) NDA or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example, new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the conditions of use associated with the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs containing the original active agent. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Sales of our products will depend, in part, on the extent to which our products will be covered by third-party payors, such as government health programs, commercial insurance and managed healthcare organizations. In the United States no uniform policy of coverage and reimbursement for drug products exists. Accordingly, decisions regarding the extent of coverage and amount of reimbursement to be provided for any of our products will be made on a payor-by-payor basis. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained.

The United States government, state legislatures and foreign governments have shown significant interest in implementing cost containment programs to limit the growth of government-paid health care costs, including price-controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs. For example, the ACA contains provisions that may reduce the profitability of drug products through increased rebates for drugs reimbursed by Medicaid programs, extension of Medicaid rebates to Medicaid managed care plans, mandatory discounts for certain Medicare Part D beneficiaries and annual fees based on pharmaceutical companies' share of sales to federal health care programs. Adoption of general controls and measures, coupled with the tightening of restrictive policies in jurisdictions with existing controls and measures, could limit payments for pharmaceutical drugs.

The Medicaid Drug Rebate Program requires pharmaceutical manufacturers to enter into and have in effect a national rebate agreement with the Secretary of the Department of Health and Human Services as a condition for states to receive federal matching funds for the manufacturer's outpatient drugs furnished to Medicaid patients. The ACA made several changes to the Medicaid Drug Rebate Program, including increasing pharmaceutical manufacturers' rebate liability by raising the minimum basic Medicaid rebate on most branded prescription drugs from 15.1% of average manufacturer price, or AMP, to 23.1% of AMP and adding a new rebate calculation for "line extensions" (i.e., new formulations, such as extended release formulations) of solid oral dosage forms of branded products, as well as potentially impacting their rebate liability by modifying the statutory definition of AMP. The ACA also expanded the universe of Medicaid utilization subject to drug rebates by requiring pharmaceutical manufacturers to pay rebates on Medicaid managed care utilization and by enlarging the population potentially eligible for Medicaid drug benefits. CMS has proposed to expand Medicaid rebate liability to the territories of the United States as well.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or the MMA, established the Medicare Part D program to provide a voluntary prescription drug benefit to Medicare beneficiaries. Under Part D, Medicare beneficiaries may enroll in prescription drug plans offered by private entities that provide coverage of outpatient prescription drugs. Unlike Medicare Part A and B, Part D coverage is not standardized. While all Medicare drug plans must give at least a standard level of coverage set by Medicare, Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs, and each drug plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level. However, Part D prescription drug formularies must include drugs within each therapeutic category and class of covered Part D drugs, though not necessarily all the drugs in each category or class. Any formulary used by a Part D prescription drug plan must be developed and reviewed by a pharmacy and therapeutic committee. Government payment for some of the costs of prescription drugs may increase demand for products for which we receive marketing approval. However, any negotiated prices for our products covered by a Part D prescription drug plan likely will be lower than the prices we might otherwise obtain. Moreover, while the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own payment rates. Any reduction in payment that results from the MMA may result in a similar reduction in payments from non-governmental payors.

For a drug product to receive federal reimbursement under the Medicaid or Medicare Part B programs or to be sold directly to U.S. government agencies, the manufacturer must extend discounts to entities eligible to participate in the 340B drug pricing program. The required 340B discount on a given product is calculated based on the AMP and Medicaid rebate amounts reported by the manufacturer. As of 2010, the ACA expanded the types of entities eligible to receive discounted 340B pricing, although, under the current state of the law, with the exception of children's hospitals, these newly eligible entities will not be eligible to receive discounted 340B pricing on orphan drugs. In addition, as 340B drug prices are determined based on AMP and Medicaid rebate data, the revisions to the Medicaid rebate formula and AMP definition described above could cause the required 340B discount to increase.

As noted above, the marketability of any products for which we receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. An emphasis on cost containment measures in the United States has increased, and we expect will continue to increase, the pressure on pharmaceutical pricing. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

In addition, in most foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing and reimbursement vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. Historically, products launched in the European Union do not follow price structures of the United States and generally prices tend to be significantly lower.

Employees and Human Capital Resources

As of the date of this Report, we had eight full-time employees, one part-time employee and five contractors, six of whom collectively comprise our management team. All but one of these individuals holds a Ph.D. or an M.D. Our employees and contractors are located in Lexington, Massachusetts, Connecticut and Atlanta, Georgia. None of our employees is represented by a labor union or covered under a collective bargaining agreement.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and additional employees. The principal purpose of our equity incentive plan is to attract, retain and motivate selected employees, consultants and directors through the granting of stock-based compensation awards.

Trademarks

We use Inhibikase Therapeutics, the Inhibikase Therapeutics logo, and other marks to represent us in the United States and other countries. We have applied to federally register our primary trademarks in our primary market, the United States. Three of the four trademark applications that we filed for (INHIBIKASE, IKT (and Design) and RAMP) have issued to registration, and the fourth application (a second application for INHIBIKASE) is allowed and is currently awaiting registration by the United States Patent and Trademark Office. We have applied to register INHIBIKASE in Australia, Canada, the EU, Japan, Switzerland and the UK. Five of the six foreign trademark applications that we filed for have issued to registration, and the sixth application is currently awaiting registration by the Canada Patent and Trademark Office. In sum, other than the three U.S. federal registrations noted above and the registrations in the ex-US territories listed above, we have not secured trademark protection for any of our trademarks or trade names in any of our other geographic markets, and failure to secure those registrations could adversely affect our business. This Annual Report on Form 10-K contains references to our logo and service marks and to those belonging to other entities. Solely for convenience, trademarks and trade names referred to in this prospectus, including logos, artwork and other visual displays, may appear without the ® or ™ symbols, but such references are not intended to indicate in any way that we will not assert, to the fullest extent under applicable law, our rights to our logo and trade names or the rights of the applicable licensor. We do not intend our use or display of other entities' names, trade names, trademarks or service marks to imply a relationship with, or endorsement or sponsorship of us by, any other entity.

Item 1A. Risk Factors.

Investing in our securities involves a high degree of risk. You should carefully consider the risks described below, as well as the other information in this document, including our financial statements and the related notes and the section titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in this document, before deciding whether to invest in our securities. The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations and growth prospects. In such an event, the market price of our securities could decline, and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations

Summary of Risks Associated with Our Business

Our business is subject to numerous risks and uncertainties that you should consider before investing in our Company.

These risks include, but are not limited to, the following:

- We are a clinical-stage drug development company with limited resources, a limited operating history and have no products approved for commercial sale, which may make it difficult to evaluate our current business and predict our future success and viability;
- If we are unable to successfully raise additional capital, our future clinical trials and product development could be limited and our long-term viability may be threatened;
- There is substantial doubt regarding our ability to continue as a going concern and our independent registered public accounting firm has included an explanatory paragraph relating to our ability to continue as a going concern in its report on our audited financial statements included in this Report. We will need to raise additional funding, which may not be available on acceptable terms, or at all. Failure to obtain this necessary capital when needed may force us to delay, limit or terminate our clinical trials or other operations;
- While the FDA lifted the clinical holds with respect to the Risvodetinib (IkT-148009) programs relating to Parkinson’s disease and MSA, we may be subject to further clinical holds by the FDA in the future;
- Drug development is a highly uncertain undertaking and involves a substantial degree of risk. We have never generated any revenue from product sales, we may never generate any revenue from product sales, and we may fail to generate further revenue from grants or contracts or to be profitable;
- The wars between Russia and Ukraine and Israel and Hamas could materially adversely affect our business, results of operations, and financial condition;
- Our results of operations have been adversely affected and, in the future, could be materially adversely impacted by the COVID-19 virus;
- Adverse developments affecting financial institutions, companies in the financial services industry or the financial services industry generally, including those we do business with, could adversely affect our operations and liquidity;
- We have incurred significant net losses since our inception and anticipate that we will continue to incur net losses for the foreseeable future;
- Due to the significant resources required for the development of our programs, and depending on our ability to access capital, we must prioritize development of certain product candidates;
- Our business is highly dependent on the success of our initial product candidates targeting neurodegenerative diseases;
- We currently contract with various research institutions to perform the research and development activities needed to develop our products, and if we ever choose to or need to find alternative research institutions, we may not be able to do so at all or, if we are able to do so, it may be costly and may cause significant delays in the development and commercialization of our products;
- Positive results from early preclinical or clinical studies of our product candidates are not necessarily predictive of the results of later preclinical studies and any current and future clinical trials of our product candidates;
- We have no history of completing clinical trials for novel drug substances or commercializing pharmaceutical products, which may make it difficult to evaluate the prospects for our future viability;

- Our clinical trials may reveal significant adverse events, toxicities or other side effects not seen in our preclinical studies and may result in a safety profile that could inhibit regulatory approval or market acceptance of any of our product candidates;
- We have concentrated much of our research and development efforts on the treatment of neurodegenerative diseases, a field that has seen limited success in drug development;
- We may encounter substantial delays in our current and planned clinical trials, or may not be able to conduct or complete our clinical trials on the timelines we expect, if at all;
- Our current and planned clinical trials may fail to demonstrate substantial evidence of the safety and efficacy of our product candidates, which would prevent, delay or limit the scope of regulatory approval and commercialization;
- Clinical development is a lengthy and expensive process with an uncertain outcome, and failure can occur at any stage of clinical development;
- The manufacture of our product candidates is complex and difficulties may be encountered in production;
- If, in the future, we are unable to establish sales and marketing capabilities or enter into agreements with third parties to sell and market any product candidates we may develop, we may not be successful in commercializing those product candidates if and when they are approved;
- Even if any product candidates we develop receive marketing approval, they may fail to achieve the degree of market acceptance by physicians, patients, healthcare payors, and others in the medical community necessary for commercial success.
- Even if we are able to commercialize any product candidates, such products may become subject to unfavorable pricing regulations, third-party reimbursement practices, or healthcare reform initiatives, which would harm our business.
- The regulatory approval processes of the FDA, EMA and comparable foreign regulatory authorities are lengthy, time consuming, and inherently unpredictable. Regulatory authorities have substantial discretion in the approval process and may refuse to accept an application, may disagree with our regulatory strategy or proposed pathway for approval or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies;
- We expect to depend in whole or in part on collaborations with third parties for the research, development and commercialization of any product candidates we may develop;
- We contract with third parties for the manufacture of materials for our research programs, preclinical studies and current clinical trials and expect to continue to do so for any future clinical trials and for commercialization of any product candidates that we may develop;
- We depend on a small number of third-party suppliers for key raw materials used in the manufacturing processes for our product candidates, and the loss of these third-party suppliers or their inability to supply us with adequate raw materials could harm our business; and
- If we are unable to obtain and maintain patent protection for any product candidates we develop, our competitors could develop and commercialize products or technology similar or identical to ours, and our ability to successfully commercialize any product candidates we may develop, and our technology may be adversely affected.

Risks Related to Our Business, Financial Condition and Capital Requirements

We are a clinical-stage drug development company with limited resources, a limited operating history and have no products approved for commercial sale, which may make it difficult to evaluate our current business and predict our future success and viability.

We are a clinical stage drug development company that commenced operations in September 2008. We have limited facilities to conduct fundamental research and we have performed our research and development activities by collaboration with contract service providers, and contract manufacturers and by designing and developing research programs in collaboration with university-based experts who work with us to evaluate mechanism(s) of disease for which we have designed and developed product candidates. Our direct research capabilities are very limited. As of the date of this document, we have not maintained a principal laboratory or primary research facility for the development of our product candidates. In addition, we have no products approved for commercial sale and therefore all of our revenue has been obtained solely through grants and contracts from private foundations and from state and federal grants from institutions such as the National Institutes of Health and the Department of Defense.

Drug development is a highly uncertain undertaking and involves a substantial degree of risk. As of the date of writing this Report we have not completed clinical trials for any of our product candidates, obtained marketing approval for any product candidates, manufactured a commercial scale product, or arranged for a third-party to do so on our behalf, or conducted sales and marketing activities necessary for successful product commercialization. Given the highly uncertain nature of drug development, we may never initiate or complete clinical trials for any of our product candidates, obtain marketing approval for any product candidates, manufacture a commercial scale product or arrange for a third-party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization.

Our limited operating history as a company makes any assessment of our future success and viability subject to significant uncertainty. We will encounter risks and difficulties frequently experienced by early-stage pharmaceutical companies in rapidly evolving fields, and we have not yet demonstrated an ability to successfully overcome such risks and difficulties. If we do not address these risks and difficulties successfully, our business, operating results and financial condition will suffer.

If we are unable to successfully raise additional capital, our future clinical trials and product development could be limited and our long-term viability may be threatened.

We experienced negative operating cash flows since our inception and funded our operations prior to our initial public offering primarily through private, state and federal contracts and grants. In December 2020, we completed an initial public offering of Common Stock, in June 2021 we completed a follow-on public offering, in January 2023 we completed a follow-on public offering and concurrent private placements (the "January 2023 Offering"), and in February 2024, we entered into an At The Market Offering Agreement with H.C. Wainwright & Co., LLC, as sales agent (the "Agent"), pursuant to which we may, from time to time, issue and sell shares of our Common Stock, in an aggregate offering price of up to \$5,659,255 through the Agent (the "ATM"). We anticipate we will need to seek additional funds in the future through equity or debt financings, or strategic alliances with third parties, either alone or in combination with equity financings to complete our product development initiatives. These financings could result in substantial dilution to the holders of our Common Stock or require contractual or other restrictions on our operations or on alternatives that may be available to us. If we raise additional funds by issuing debt securities, these debt securities could impose significant restrictions on our operations. Any such required financing may not be available in amounts or on terms acceptable to us, and the failure to procure such required financing could have a material and adverse effect on our business, financial condition and results of operations, or threaten our ability to continue as a going concern.

Our present and future capital requirements will be significant and will depend on many factors, including:

- the progress and results of our development efforts for our product candidates;
- the costs, timing and outcome of regulatory review of our product candidates;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims;
- the effect of competing technological and market developments;
- market acceptance of our product candidates;
- the rate of progress in establishing coverage and reimbursement arrangements with domestic and international commercial third-party payors and government payors;

- the extent to which we acquire or in-license other products and technologies; and
- legal, accounting, insurance and other professional and business-related costs.

We may not be able to acquire additional funds on acceptable terms, or at all. If we are unable to raise adequate funds, we may have to liquidate some or all of our assets or delay, reduce the scope of or eliminate some or all of our development programs.

If we do not have, or are not able to obtain, sufficient funds, we may be required to delay development or commercialization of our product candidates. We also may have to reduce the resources devoted to our product candidates or cease operations. Any of these factors could harm our operating results.

There is substantial doubt regarding our ability to continue as a going concern and our independent registered public accounting firm has included an explanatory paragraph relating to our ability to continue as a going concern in its report on our audited financial statements included in this Report. We will need to raise additional funding, which may not be available on acceptable terms, or at all. Failure to obtain this necessary capital when needed may force us to delay, limit or terminate our clinical trials or other operations.

We have incurred net losses and used significant cash in operating activities since inception, and we expect to continue to generate operating losses for the foreseeable future. As of December 31, 2023, we had an accumulated deficit of \$66,900,725. As of December 31, 2023, we had cash and cash equivalents of \$9,165,179 and marketable securities of \$4,086,873, which we believe that, together with the net proceeds of ATM, should be sufficient to fund our operating expenses into the first quarter of 2025. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. Pursuant to the requirements of Accounting Standards Codification (ASC) 205-40, Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern, and as a result of our financial condition and other factors described herein, there is substantial doubt about our ability to continue as a going concern. Our ability to continue as a going concern will depend on our ability to obtain additional funding, as to which no assurances can be given. Our future success depends on our ability to raise capital and/or execute our current operating plan. However, we cannot be certain that these initiatives or raising additional capital, will be available to us or, if available, will be on terms acceptable to us. If we issue additional securities to raise funds, these securities may have rights, preferences, or privileges senior to those of our common stock, and our current shareholders may experience dilution. If we are unable to obtain funds when needed or on acceptable terms, we may be required to curtail our current clinical trials, cut operating costs, forego future development and other opportunities or even terminate our operations, which may involve seeking bankruptcy protection. We have identified conditions and events that raise doubt about our ability to continue as a going concern and our independent registered public accounting firm has included an explanatory paragraph relating to our ability to continue as a going concern in its report on our audited financial statements for the years ended December 31, 2023 and 2022 included in this Report.

Drug development is a highly uncertain undertaking and involves a substantial degree of risk. We have never generated any revenue from product sales, we may never generate any revenue from product sales, and we may fail to generate further revenue from grants or contracts or to be profitable.

We have no products approved for commercial sale and have not generated any revenue from product sales. We anticipate generating additional revenue from private foundations and state and federal grants and contracts prior to generating revenue from product sales, but such grants and contracts are not guaranteed and will not make us profitable. Our ability to successfully commercialize our existing product candidates depends on our ability to successfully obtain regulatory approvals, among other factors. Thus, we may not generate meaningful revenue until after we have successfully begun and completed clinical development and received regulatory approval for the commercial sale of a product candidate. We may never begin clinical development or receive regulatory approval for the commercial sale of a product candidate and thus may never generate revenue from product sales.

Our ability to generate revenue and achieve profitability depends significantly on many factors, including:

- successfully completing research and preclinical and clinical development of our product candidates;
- obtaining regulatory approvals and marketing authorizations for product candidates once we have successfully begun and completed clinical development and clinical trials;
- identifying, assessing, acquiring and/or developing new product candidates;
- successfully competing for grant revenue from private foundations and state and federal agencies;
- negotiating favorable terms in any collaboration, licensing or other arrangements into which we may enter;

- launching and successfully commercializing product candidates for which we obtain regulatory and marketing approval, either by collaborating with a partner or, if launched independently, by establishing a sales, marketing and distribution infrastructure;
- obtaining and maintaining an adequate price for our product candidates, both in the United States and in foreign countries where our products are commercialized;
- obtaining adequate reimbursement for our product candidates from payors;
- obtaining market acceptance of our product candidates as viable treatment options;
- addressing any competing technological and market developments;
- maintaining, protecting, expanding and enforcing our portfolio of intellectual property rights, including patents, trade secrets and know-how; and
- attracting, hiring and retaining qualified personnel.

Because of the numerous risks and uncertainties associated with drug development, we are unable to predict the timing or amount of our expenses, or when, if ever, we will be able to generate any meaningful revenue or achieve or maintain profitability. In addition, our expenses could increase beyond our current expectations if we are required by the FDA or foreign regulatory agencies to perform studies in addition to those that we currently anticipate, or if there are any delays in any of our or our future collaborators' preclinical or clinical trials or the development of any of our product candidates. Even if one or more of our product candidates is approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product candidate and ongoing compliance efforts.

Even if we are able to generate revenue from the sale of any approved products, we may not become profitable and may need to obtain additional funding to continue operations. Revenue from the sale of any product candidate for which regulatory approval is obtained will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval, the accepted price for the product, the ability to get reimbursement at any price and whether we own the commercial rights for that territory. If the number of addressable patients is not as significant as we anticipate, the indication approved by regulatory authorities is narrower than we expect, or the reasonably accepted population for treatment is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of such products, even if approved. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis.

Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our pipeline of product candidates or continue our operations, and cause a decline in the value of our Common Stock, all or any of which may adversely affect our viability.

Geopolitical instability and ongoing military conflicts, including the conflict between Russia and Ukraine and the conflict between Israel and Hamas could materially adversely affect our business, results of operations, and financial condition.

In February 2022, Russian military forces invaded Ukraine, and in October 2023, Israel launched a military response against Hamas in Gaza. Although the length, impact, and outcome of these ongoing conflicts is highly unpredictable, they have led, and could continue to lead, to significant market and other disruptions, including instability in financial markets, supply chain interruptions, political and social instability, and increases in cyberattacks, intellectual property theft, and espionage. We are actively monitoring the situations in Ukraine and Gaza and assessing their impact on our business.

We have no way to predict the progress or outcome of these conflicts, as they, and any resulting government reactions, are rapidly developing and beyond our control. The extent and duration of the conflicts, sanctions, and resulting market disruptions could be significant and could potentially have a substantial impact on the global economy and our business for an unknown period of time. Any of the above-mentioned factors could materially adversely affect our business, financial condition, and results of operations. Any such disruptions may also magnify the impact of other risks described in this "Risk Factors" section and elsewhere in this Annual Report on Form 10-K.

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

Our business and results of operations could be adversely impacted by epidemics or pandemics, such as COVID-19, particularly if there are closures or other restrictions in the places where we or our manufacturers and suppliers operate. For example, we have in the past and may in the future experience impacts to certain of our suppliers as a result of the COVID-19 pandemic or other health epidemics or outbreaks occurring in one or more of locations, which may materially and adversely affect our business, financial condition and results of operations. Further, our operation has in the past and may in the future experience disruptions, including in connection with temporary office closures and suspension of services by our suppliers, which may result in us having to procure the components for our product candidates from alternate suppliers, which may materially and adversely affect our development timelines, and our business, financial condition and results of operations. Pandemics may also have adverse consequences for clinical trials, including the drop-out of subjects or inability to attract subjects. While we believe we have generally recovered from the adverse impact that the COVID-19 pandemic had on our business during 2020, we believe that the COVID-19 virus could continue to adversely impact our results of operations, cash flows and financial condition in the future, and it is likely that we will still need to make adjustments to our operating plans in reaction to developments that are beyond our control.

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

Actual events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds, have in the past and may in the future lead to market-wide liquidity problems. For example, on March 10, 2023, Silicon Valley Bank was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation, or the FDIC, as receiver.

Our access to our cash and cash equivalents and our ability to access bank financing in amounts adequate to finance our operations could be significantly impaired by the financial institutions with which we have arrangements directly facing liquidity constraints or failures. In addition, investor concerns regarding the U.S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire or take down financing on acceptable terms or at all. Any material decline in available funding or our ability to access our cash and cash equivalents or our ability to access bank financing could adversely impact our ability to meet our operating expenses and result in breaches of our contractual obligations which could have material adverse impacts on our operations and liquidity.

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

We have incurred net losses since our inception, including net losses of \$19,028,883 and \$18,054,155 for the years ended December 31, 2023 and 2022, respectively. As of December 31, 2023, we had an accumulated deficit of \$66,900,725.

We have invested significant financial resources in research and development activities, including for our product candidates and our RAMPTM drug discovery program and prodrug technologies. We do not expect to generate revenue from product sales for several years, if at all. The amount of our future net losses will depend, in part, on the level of our future expenditures and our ability to generate revenue. Moreover, our net losses may fluctuate significantly from quarter to quarter and year to year, such that a period-to-period comparison of our results of operations may not be a good indication of our future performance.

We expect to continue to incur significant expenses and increasingly higher operating losses for the foreseeable future. We anticipate that our expenses will increase substantially if and as we:

- continue our research and discovery activities;
- continue dosing patients in our Phase II clinical trial of Risvodetinib (IkT-148009);
- continue the development of our RAMPTM drug discovery platform and prodrug technologies;
- advance our current and any future product candidates through preclinical and clinical development;
- initiate and conduct additional preclinical, clinical or other studies for our product candidates;
- work with our contract manufacturers to scale up the manufacturing processes for our product candidates or, in the future, establish and operate a manufacturing facility;

- change or add additional contract manufacturers or suppliers;
- seek regulatory approvals and marketing authorizations for our product candidates;
- establish sales, marketing and distribution infrastructure to commercialize any products for which we obtain approval;
- acquire or in-license product candidates, intellectual property and technologies;
- make milestone, royalty or other payments due under any license or collaboration agreements;
- obtain, maintain, protect and enforce our intellectual property portfolio, including intellectual property obtained through license agreements;
- attract, hire and retain qualified personnel;
- provide additional internal infrastructure to support our continued research and development operations and any planned commercialization efforts in the future;
- experience any delays or encounter other issues related to our operations;
- experience negative general market conditions or extraordinary external events, such as recessions or the COVID-19 pandemic;
- meet the requirements and demands of being a public company; and
- defend against any product liability claims or other lawsuits related to our products.

Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' deficit and working capital. In any particular quarter or quarters, our operating results could be below the expectations of securities analysts or investors, which could cause our stock price to decline.

If we fail to obtain additional financing, we may be unable to complete the development of and, if approved, commercialization of our product candidates.

Our operations have required substantial amounts of cash since inception. Prior to our initial public offering, we financed our operations primarily through revenue generated by private, state and federal grants and contracts and subsequently through the issuance of securities in our December 2020 initial public offering, our June 2021 follow-on public offering, our January 2023 Offering and through our At-The-Market (ATM) offering. Developing our product candidates is expensive, and we expect to continue to spend substantial amounts as we fund our early-stage research projects, continue preclinical development of our early-stage programs and, in particular, advance our lead program candidates through preclinical development and clinical trials, including our Phase 2 clinical trial of Risvodetinib (IKT-148009). The successful development of our product candidates, obtaining regulatory approvals and launching and commercializing any product candidate will require substantial additional funding beyond the net proceeds of our securities offerings.

The Company had cash and cash equivalents of \$9,165,179 and marketable securities of \$4,086,873 as of December 31, 2023. Our estimate as to how long we expect our working capital to be adequate to fund our operations is based on assumptions that may prove inaccurate, and we could use our available capital resources sooner than we currently expect. In addition, changing circumstances may cause us to increase our spending significantly faster than we currently anticipate, and we may need to spend more money than currently expected because of circumstances beyond our control or if we choose to expand more rapidly than we presently anticipate.

We will require additional capital for the further development and, if approved, commercialization of our product candidates. Additional capital may not be available when we need it, on terms acceptable to us, or at all. We have no committed source of additional capital. If adequate capital is not available to us on a timely basis, we may be required to significantly delay, scale back or discontinue our research and development programs or the commercialization of any product candidates, if approved, or be unable to continue or expand our operations or otherwise capitalize on our business opportunities, as desired, which could materially affect our business, prospects, financial condition and results of operations and cause the price of our common stock to decline. Market volatility resulting from the COVID-19 pandemic or other factors could also adversely impact our ability to access capital as and when needed.

Furthermore, debt financing, if available, may require payment of interest and potentially involve restrictive covenants that could impose limitations on our flexibility to operate. Any difficulty or failure to successfully obtain additional funding may jeopardize our ability to continue the business and our operations.

Due to the significant resources required for the development of our programs, and depending on our ability to access capital, we must prioritize development of certain product candidates. We may expend our limited resources on programs that do not yield a successful product candidate and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

We seek to maintain a process of prioritization and resource allocation to maintain an optimal balance between aggressively advancing lead programs and ensuring replenishment of our portfolio. We have multiple programs in clinical development across two primary assets, Risvodetinib (IkT-148009) and IkT-001Pro.

Due to the significant resources required for the development of our programs, we must focus our programs on specific diseases and disease pathways and decide which product candidates to pursue and advance and the amount of resources to allocate to each. Our decisions concerning the allocation of research, development, collaboration, management and financial resources toward particular product candidates or therapeutic areas may not lead to the development of any viable commercial product and may divert resources away from better opportunities. Similarly, our potential decisions to delay, terminate or collaborate with third parties in respect of certain programs may subsequently also prove to be suboptimal and could cause us to miss valuable opportunities. We may fail to capitalize on viable commercial products or profitable market opportunities, be required to forego or delay pursuit of opportunities with other product candidates or other diseases and disease pathways that may later prove to have greater commercial potential than those we choose to pursue, or relinquish valuable rights to such product candidates through collaboration, licensing or other royalty arrangements in cases in which it would have been advantageous for us to invest additional resources to retain sole development and commercialization rights. If we make incorrect determinations regarding the viability or market potential of any or all of our programs or product candidates or misread trends in the pharmaceutical industry, in particular, for neurodegenerative diseases, our business, prospects, financial condition and results of operations could be materially adversely affected.

Our business is highly dependent on the success of our initial product candidates targeting neurodegenerative diseases. All of our product candidates will require significant nonclinical and clinical development before we can seek regulatory approval for and launch a product commercially.

Our business and future success depends on our ability to obtain regulatory approval of, and then successfully launch and commercialize our initial product candidates targeting neurodegenerative diseases, including Risvodetinib (IkT-148009) and IkT-001Pro. Our product candidates, including Risvodetinib (IkT-148009), may experience preliminary complications surrounding trial execution, such as complexities surrounding the submission and regulatory acceptance of INDs, trial protocols and design, patient recruitment and enrollment, quality and supply of clinical doses and safety issues.

All of our product candidates are in the early stages of preclinical and/or clinical development and will require additional nonclinical and clinical development, regulatory review and approval in multiple jurisdictions, substantial investment, access to sufficient commercial manufacturing capacity and significant marketing efforts, all of which will require additional capital, before we can generate any revenue from product sales. In addition, if Risvodetinib (IkT-148009) encounters safety, efficacy, supply or manufacturing problems, developmental delays, regulatory or commercialization issues or other problems, our development plans and business would be significantly harmed.

While the FDA lifted the clinical holds with respect to the Risvodetinib (IkT-148009) program relating to Parkinson's disease and Multiple System Atrophy, we may be subject to further clinical holds by the FDA in the future.

On November 7, 2022, the FDA informed the Company that it had reviewed the Company's Investigational New Drug ("IND") application for Risvodetinib (IkT-148009) for the treatment of Multiple Systems Atrophy ("MSA") and had issued a clinical hold on the Risvodetinib (IkT-148009) 201 program in Parkinson's disease ("PD") and the use of Risvodetinib (IkT-148009) in MSA.

In January 2023, the FDA lifted its clinical hold on the Risvodetinib (IkT-148009) program based on the Company's complete response and amendment dated December 21, 2022, as well as further commitments on January 20, 2023 regarding ophthalmologic monitoring in the protocol of study Risvodetinib (IkT-148009)-201 and various modifications to the Investigator Brochure. In January 2023, the Company initiated its Phase 2 program, termed 'the 201 trial' (www.the201trial.com), for Risvodetinib (IkT-148009) as a treatment for Parkinson's disease and began the process of opening sites in the U.S.

Although the clinical hold on the Risvodetinib (IkT-148009) program has been lifted, we can provide no assurance that we will not be subject to a clinical hold. Further, the FDA or other regulatory agencies may continue to express safety concerns after the hold is lifted, and future preclinical or clinical studies involving Risvodetinib (IkT-148009) may be more burdensome or include additional preclinical or clinical endpoints that are difficult to meet. In such instances, our progress in the development of this program may be

significantly slowed and the associated costs may be significantly increased, which could adversely affect our business, prompt us to cease development of this program entirely and cause our stock price to decline.

Risks Related to the Discovery, Development and Commercialization of Our Product Candidates

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

We do not currently own, lease or operate a principal laboratory, research and development or manufacturing facility of our own. Currently, we collaborate with various research institutions to perform research and development for our products, including Johns Hopkins University, Arizona State University and Michigan State University. Establishing our own facilities would result in significant additional expense and may result in potential delays in testing and production. Building and operating our own production facilities would require substantial additional funds and other resources, of which there can be no assurance that we will be able to obtain. In addition, there can be no assurances that we would be able to enter into any arrangement with third parties to manufacture our product, if any, on acceptable terms or at all. The commercial success of products outside the United States will also be dependent on the successful completion of arrangements with future partners, licensees or distributors in each territory. There can be no assurance that we will be successful in continuing to contract with research institutions to perform research and development for our products, that we would be able to establish our own facilities should we choose to or find it necessary to do so, that we would be successful in establishing additional collaborative arrangements or that, if established, such future partners will be successful in commercializing our products.

Research, development, and commercialization of pharmaceutical products is inherently risky. We are heavily dependent on the successful use of our RAMP™ drug discovery program and the product candidates that emerge from it and which are undergoing preclinical development. We cannot give any assurance that any of our product candidates will receive regulatory approval, which is necessary before they can be commercialized.

We are at an early stage of development of the product candidates currently in our programs and are further developing our RAMP™ drug discovery program and prodrug technologies to provide future additional product candidates. To date, we have invested substantially all of our efforts and financial resources to identify, develop intellectual property for, and advance our programs, including conducting preclinical studies for our lead programs, commencing our clinical trials for Risvodetinib (IKT-148009) and providing general and administrative support for these operations. Our future success is dependent on our ability to successfully develop, obtain regulatory approval for, and then successfully commercialize our product candidates, and we may fail to do so for many reasons, including the following:

- our product candidates may not successfully complete preclinical studies or begin or complete clinical trials;
- our product candidates may fail to be delivered across the blood brain barrier, or BBB, and therefore may not be clinically viable for CNS diseases such as PD;
- a product candidate may, on further study, be shown to have harmful side effects or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria;
- our competitors may develop therapeutics that render our product candidates obsolete or less attractive;
- our competitors may develop alternative technologies to deliver therapeutics across the BBB that outperform our product candidates;
- the product candidates that we develop may not be sufficiently covered by intellectual property for which we hold exclusive rights;
- the product candidates that we develop may be covered by third parties' patents or other intellectual property or exclusive rights;
- the market for a product candidate may change so that the continued development of that product candidate is no longer reasonable or commercially attractive;
- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; if a product candidate obtains regulatory approval, we may be unable to establish sales and marketing capabilities, or successfully market such approved product candidate, to gain market acceptance; and a product candidate may not be accepted as safe and effective by patients, the medical community or governmental third-party payors.

We may not be successful in our efforts to further develop current or future product candidates. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from the FDA or comparable foreign regulatory authorities, and we may never receive such regulatory approval for any of our product candidates. Each of our product candidates will require significant clinical development, management of preclinical, clinical, and manufacturing activities, regulatory approval, adequate manufacturing supply, a commercial organization, and significant marketing efforts before we generate any revenue from product sales, if at all.

If any of these events occur, we may be forced to abandon our development efforts for a program or programs, which could have a material adverse effect on our business and could potentially cause us to cease operations.

Positive results from early clinical or preclinical studies of our product candidates are not necessarily predictive of the results of later preclinical studies and any current and future clinical trials of our product candidates. If we cannot show positive results or replicate any positive results from our earlier clinical or preclinical studies of our product candidates in our later preclinical studies and current and future clinical trials, we may be unable to successfully develop, obtain regulatory approval for and commercialize our product candidates.

Any positive results from clinical or preclinical studies of our product candidates may not necessarily be predictive of the results from later preclinical studies and current and future clinical trials. Similarly, even if we are able to complete our planned preclinical studies or any future clinical trials of our product candidates according to our current development timeline, the positive results from such clinical or preclinical studies and current and future clinical trials of our product candidates may not be replicated in subsequent preclinical studies or clinical trial results.

Many companies in the pharmaceutical industry have suffered significant setbacks in late-stage clinical trials after achieving positive results in early-stage development and we cannot be certain that we will not face similar setbacks. These setbacks have been caused by, among other things, preclinical findings made while clinical trials were underway, or safety or efficacy observations made in preclinical studies and clinical trials, including previously unreported adverse events. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials nonetheless failed to obtain regulatory approval.

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

Our operations to date have been limited to research, financing and staffing our company, developing our technology and developing our lead product candidate, Risvodetinib (IkT-148009), and other product candidates and commencing our Phase I and Phase II clinical trials for Risvodetinib (IkT-148009). Our company has completed observational trials measuring biological parameters for specific indications in human patients from human fluids, but we have never completed a clinical development program for a new interventional drug, and we have not commercialized product candidates. Our product development strategy has included attempts to create molecules through RAMP™ that have predictable human safety margins for the target patient population, but we have never proved that our product candidates have this safety margin in clinical studies all the way through drug approval. We have not conducted pivotal clinical studies for any novel drug candidate and it may be years before any such trials is initiated, if at all. We cannot be certain that planned clinical trials will begin or be completed on time, if at all, that our planned development programs would be acceptable to the FDA or other regulatory authorities, or that, if approval is obtained, such product candidates can be successfully commercialized. Clinical trials and commercializing our product candidates will require significant additional financial and management resources, and reliance on third party clinical investigators, contract research organizations or CROs, consultants or collaborators. Relying on third party clinical investigators, CROs or collaborators may result in delays that are outside of our control. If our clinical development program, clinical trials or commercialization of our product candidates were to fail, it would have a material adverse effect on our business, prospects, financial condition and results of operations.

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

In order to obtain marketing approval for any of our product candidates, we must demonstrate the safety and efficacy of the product candidate for the relevant clinical indication or indications through clinical trials as well as additional supporting data. If our product candidates are associated with undesirable side effects in clinical trials or have characteristics that are unexpected, we may need to interrupt, delay or abandon their development or limit development to more narrow uses or sub populations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective.

We cannot guarantee that any positive results in preclinical studies will successfully translate to human patients. Additionally, we cannot guarantee that additional preclinical studies will show positive results. It is not uncommon to observe results in human clinical trials that are unexpected based on preclinical testing, and many product candidates fail in clinical trials despite promising preclinical results. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval for their products. Subjects in our planned clinical trials may suffer significant adverse events or other side effects not observed in our preclinical studies or earlier clinical trials. The observed potency and kinetics of our product candidates in preclinical studies may not be observed in human clinical trials. We have tested the dosing frequency and route of administration of our product candidates in preclinical studies, which will inform our dosing strategy for future clinical trials. However, such dose and route of administration may not result in sufficient exposure or pharmacological effect in humans, and may lead to unforeseen toxicity not previously observed in preclinical testing. Further, if our planned clinical trials of our product candidates fail to demonstrate efficacy to the satisfaction of regulatory authorities or do not otherwise produce positive results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.

If significant adverse events or other side effects are observed in any of our current and future clinical trials, we may have difficulty recruiting patients to the related clinical trial, patients may drop out of the trial, or we may be required to abandon the trial or our development efforts of that product candidate altogether. We, the FDA or other applicable regulatory authorities, or an institutional review board may suspend clinical trials of a product candidate at any time for various reasons, including a belief that subjects in such trials are being exposed to unacceptable health risks or adverse side effects. Some potential therapeutics developed in the pharmaceutical industry that initially showed therapeutic promise in early-stage studies have later been found to cause side effects that prevented their further development. Even if the side effects do not preclude the drug from obtaining or maintaining marketing approval, undesirable side effects may inhibit market acceptance of the approved product due to its tolerability versus other therapies. Any of these developments could materially harm our business, financial condition and prospects.

Further, if any of our product candidates obtains marketing approval, toxicities associated with our product candidates may also develop after such approval and lead to a requirement to conduct additional clinical safety trials, additional warnings being added to the labeling, significant restrictions on the use of the product or the withdrawal of the product from the market. We cannot predict whether our product candidates will cause toxicities in humans that would preclude or lead to the revocation of regulatory approval.

We may not be successful in our efforts to continue to create a pipeline of product candidates or to develop commercially successful products. If we fail to successfully identify and develop additional product candidates, our commercial opportunity may be limited.

One of our strategies is to identify and pursue clinical development of additional product candidates. All of our programs are in the research, discovery, preclinical or clinical stages of development. Identifying, developing, obtaining regulatory approval and commercializing additional product candidates will require substantial additional funding beyond the current financial resources of the Company and is prone to the risks of failure inherent in drug development. We may not be able to successfully identify or acquire additional product candidates, advance any of these additional product candidates through the development process, successfully commercialize any such additional product candidates, if approved. If we are unable to successfully identify, acquire, develop and commercialize additional product candidates, our commercial opportunity may be limited.

If any of our product candidates successfully completes its planned clinical trials, we plan to seek regulatory approval to market such product candidates in the United States, the European Union, or EU, and in additional foreign countries where we believe there is a viable commercial opportunity. We have never commenced, compiled or submitted an application seeking regulatory approval to market any product candidate. We may never receive regulatory approval to market any product candidates even if such product candidates successfully complete clinical trials, which would adversely affect our viability. To obtain regulatory approval in countries outside the United States, we must comply with numerous and varying regulatory requirements of such other countries regarding safety, efficacy, chemistry, manufacturing and controls, clinical trials, commercial sales, pricing, and distribution of our product candidates. We may also rely on collaborators or partners to conduct the required activities to support an application for regulatory approval, and to seek approval, for one or more of our product candidates. We cannot be sure that collaborators or partners will conduct these activities or do so within the time frame we desire. Even if we (or our collaborators or partners) are successful in obtaining approval in one jurisdiction, we cannot ensure that we will obtain approval in any other jurisdictions. If we are unable to obtain approval for our product candidates in multiple jurisdictions, our revenue and results of operations could be negatively affected.

Even if we receive regulatory approval to market any of our product candidates, whether for the treatment of neurodegenerative diseases or other diseases, we cannot assure you that any such product candidate will be successfully commercialized, widely accepted in the marketplace or more effective than other commercially available alternatives.

Investment in pharmaceutical product development involves significant risk that any product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval, and become commercially viable. We cannot provide any assurance that we will be able to successfully advance any of our product candidates through the development process or, if approved, successfully commercialize any of our product candidates.

We have concentrated much of our research and development efforts on the treatment of neurodegenerative diseases, a field that has seen limited success in drug development.

We have focused much of our research and development efforts on addressing neurodegenerative diseases. Collectively, efforts by pharmaceutical companies in the field of neurodegenerative diseases have seen limited success in drug development. There are currently no marketed disease-modifying therapeutic options available for patients with PD and other neurodegenerative diseases. Disease-modifying therapies are therapies that would slow, stop or reverse neurodegenerative disease. While we believe our approach to therapy is disease-modifying, no markers to quantify disease progression have been identified. Our future success may be dependent on demonstrating disease-modification for neurodegenerative diseases using our product candidates. Developing and, if approved, commercializing our product candidates for treatment of neurodegenerative disease subjects us to a number of challenges, including engineering product candidates to cross the BBB to enable optimal concentration of the therapeutic in the brain and obtaining regulatory approval from the FDA and other regulatory authorities who have only a limited set of precedents to rely on.

Our approach to the treatment of neurodegenerative diseases aims to identify and select targets with a biochemical link to neurodegenerative diseases, identify and develop biomarkers for the intended targets, which are biological molecules found in blood, other bodily fluids or tissues that are signs of a normal or abnormal process or of a condition or disease, to select the right patient population and demonstrate target engagement, pathway engagement and impact on disease progression of our molecules, identify and develop molecules that engage the intended target, and engineer our molecules to cross the BBB and act directly in the brain. This strategy may not prove to be successful. We cannot be sure that our approach will yield satisfactory therapeutic products that are safe and effective, scalable, profitable or able to obtain regulatory approval.

Moreover, public perception of drug safety issues, including adoption of new therapeutics or novel approaches to treatment, may adversely influence the willingness of subjects to participate in clinical trials, or if approved, of physicians to subscribe to novel treatments.

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

Our current and planned clinical trials are expensive, time consuming, and subject to uncertainty. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all. We cannot be sure that submission of an IND, or, in the case of the EMA, a clinical trial application, or CTA, will result in the FDA or EMA allowing clinical trials to begin in a timely manner, if at all. Moreover, even if these trials begin, issues may arise that could suspend or terminate such clinical trials. A failure of one or more clinical trials can occur at any stage of testing, and our future clinical trials may not be successful. Events that may prevent successful or timely initiation or completion of clinical trials include:

- inability to generate sufficient preclinical, toxicology, or other in vivo or in vitro data to support the initiation or continuation of clinical trials;
- delays in confirming target engagement, patient selection or other relevant biomarkers to be utilized in preclinical and clinical product candidate development;
- delays in reaching a consensus with regulatory agencies on study design;
- delays in reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;
- delays in identifying, recruiting and training suitable clinical investigators;
- delays in obtaining required IRB approval at each clinical trial site;

- imposition of a temporary or permanent clinical hold by regulatory agencies for a number of reasons, including, but not limited to, after review of an IND or amendment, CTA or amendment, or equivalent application or amendment; as a result of a new safety finding that presents unreasonable risk to clinical trial participants; a negative finding from an inspection of our clinical trial operations or study sites; developments in trials conducted by competitors that raise FDA or EMA concerns about risk to patients broadly; or if the FDA or EMA finds that the investigational protocol or plan is clearly deficient to meet its stated objectives;
- delays or difficulties resulting from the COVID-19 pandemic or other future pandemics;
- delays in identifying, recruiting and enrolling suitable patients to participate in our clinical trials, and delays caused by patients withdrawing from clinical trials or failing to return for post-treatment follow-up;
- difficulty collaborating with patient groups and investigators;
- failure by our CROs, other third parties, or us to adhere to clinical trial requirements;
- failure to perform in accordance with the FDA's or any other regulatory authority's current good clinical practices, or cGCPs, requirements, or applicable EMA or other regulatory guidelines in other countries;
- occurrence of adverse events associated with a product candidate that are viewed to outweigh its potential benefits;
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols;
- changes in the standard of care on which a clinical development plan was based, which may require new or additional trials;
- the cost of clinical trials of our product candidates being greater than we anticipate;
- clinical trials of our product candidates producing negative or inconclusive results, which may result in our deciding, or regulators requiring us, to conduct additional clinical trials or abandon product development programs; and
- delays in manufacturing, testing, releasing, validating, or importing/exporting sufficient stable quantities of our product candidates for use in clinical trials or the inability to do any of the foregoing.

Any inability to successfully initiate or complete current or future clinical trials could result in additional costs to us or impair our ability to generate revenue. In addition, if we make manufacturing or formulation changes to our product candidates, we may be required to or we may elect to conduct additional studies to bridge our modified product candidates to earlier versions. Clinical trial delays could also shorten any periods during which our product shave patent protection and may allow our competitors to bring products to market before we do, which could impair our ability to successfully commercialize our product candidates and may harm our business and results of operations.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the data safety monitoring board for such trial or by the FDA, EMA or any other regulatory authority, or if the IRBs of the institutions in which such trials are being conducted suspend or terminate the participation of their clinical investigators and sites subject to their review. Such authorities may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA, EMA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product candidate, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

We may encounter difficulties enrolling patients in our current and planned clinical trials, and our clinical development activities could thereby be delayed or otherwise adversely affected.

The timely completion of our current and planned clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in such trials until their conclusion. We may experience difficulties in patient enrollment in our planned clinical trials for a variety of reasons, including:

- the size and nature of the patient population;
- the patient eligibility criteria defined in the protocol, and/or certain criteria related to stage of disease progression, which may limit the patient populations eligible for our clinical trials;
- the size of the study population required for analysis of a trial's primary endpoints;
- the proximity of patients to a trial site;

- the COVID-19 pandemic or other future pandemics;
- the design of a trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- competing clinical trials for similar therapies or targeting patient populations meeting our patient eligibility criteria;
- clinicians' and patients' perceptions as to the potential advantages and side effects of the product candidate being studied in relation to other available therapies and product candidates;
- our ability to obtain and maintain patient consents; and
- the risk that patients enrolled in clinical trials will not complete such trials, for any reason.

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

Before obtaining regulatory approvals for the commercial sale of any of our product candidates, we must demonstrate through lengthy, complex and expensive preclinical studies and clinical trials that our product candidates are both safe and effective for use in each target indication. Each product candidate must demonstrate an adequate risk versus benefit profile in its intended patient population and for its intended use.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical studies of our product candidates may not be predictive of the results of early-stage or later-stage clinical trials, and results of early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. The results of our planned clinical trials in one set of patients or disease indications may not be predictive of those obtained in another. In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the dosing regimen and other clinical trial protocols and the rate of dropout among clinical trial participants. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy profile despite having progressed through preclinical studies and initial clinical trials. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unacceptable safety issues, notwithstanding promising results in earlier trials. This is particularly true in neurodegenerative diseases, where failure rates historically have been higher than in many other disease areas. Most product candidates that begin clinical trials are never approved by regulatory authorities for commercialization.

We cannot be certain that our current or planned clinical trials will be successful. Additionally, any safety concerns observed in any one of our current and planned clinical trials in our targeted indications could limit the prospects for regulatory approval of our product candidates in those and other indications, which could have a material adverse effect on our business, prospects, financial condition and results of operations.

Even if our planned clinical trials were to be successfully completed, we cannot guarantee that the FDA or foreign regulatory authorities will interpret the results as we do, and more trials could be required before we submit our product candidates for approval. To the extent that the results of the trials are not satisfactory to the FDA or foreign regulatory authorities for support of a marketing application, we may be required to expend significant resources, which may not be available to us, to conduct additional trials in support of potential approval of our product candidates. Even if regulatory approval is secured for any of our product candidates, the terms of such approval may limit the scope and use of our product candidate, which may also limit its commercial potential.

Clinical development is a lengthy and expensive process with an uncertain outcome, and failure can occur at any stage of clinical development. If we are unable to design, conduct and complete our current and planned clinical trials successfully, our product candidates will not be able to receive regulatory approval.

In order to obtain FDA approval for any of our product candidates, we must submit to the FDA an NDA with substantial evidence that demonstrates that the product candidate is both safe and effective in humans for its intended use. This demonstration will require significant research, preclinical studies and clinical trials.

Clinical trials are time-consuming, expensive, and difficult to design and implement, in part because they are subject to rigorous requirements and the outcomes are inherently uncertain. Clinical testing may take many years to complete, and failure can occur at any time during the clinical trial process, even with active ingredients that have previously been approved by the FDA as safe and effective. If we receive authorization to conduct our planned clinical trials in addition to our already commenced Phase I and Phase II clinical trials and our two-part dose finding/dose equivalence study for IKT-001Pro, we could encounter problems that could halt our planned clinical trials or require us to repeat such clinical trials. If patients participating in our current and planned clinical trials suffer drug-related adverse actions during the course of such clinical trials, or if we or the FDA believe that patients are being exposed to unacceptable health risks, such clinical trials may have to be suspended or terminated. Suspension, termination or the need to repeat a clinical trial can occur at any stage.

The clinical trial success of each of our product candidates depends on reaching statistically significant changes in patients' symptoms based on clinician-rated scales. There is a lack of consensus regarding standardized processes for assessing clinical outcomes based on clinician-rated scales. Accordingly, the scores from our clinical trials may not be reliable, useful or acceptable to the FDA or other regulatory agencies.

Changes in standards related to clinical trial design could have a material adverse effect on our ability to design and conduct clinical trials as planned. For example, we expect to conduct clinical trials comparing our product candidates to both placebo and other approved drugs, but regulatory authorities may not allow us to compare our product candidates to a placebo in a particular clinical indication where approved products are available. In that case, both the cost and the amount of time required to conduct such a planned clinical trial could increase. The FDA may disagree with our trial design and our interpretation of data from our planned clinical trials or may change the requirements for approval even after it has reviewed and commented on the design for our planned clinical trials. The FDA may also approve a product candidate for fewer or more limited indications than we request or may grant approval contingent on the performance of costly post-approval clinical trials. In addition, the FDA may not approve the labeling claims or removal of certain warnings that we believe are necessary or desirable for the successful commercialization of our product candidates. Approval may be contingent on a Risk Evaluation and Mitigation Strategy, or REMS, which could have a material adverse effect on the labeling, distribution or promotion of a drug product.

Any of these delays or additional requirements could cause our product candidates to not be approved, or if approved, significantly impact the timing and commercialization of our product candidates and significantly increase our overall costs of drug development.

We face significant competition in an environment of rapid technological and scientific change, and there is a possibility that our competitors may achieve regulatory approval before us or develop therapies that are safer, more advanced or more effective than ours, which may negatively impact our ability to successfully market or commercialize any product candidates we may develop and ultimately harm our financial condition.

The development and commercialization of new drug products is highly competitive. Moreover, the neurodegenerative field is characterized by strong and increasing competition, and a strong emphasis on intellectual property. Our competitors may be able to develop other compounds, drugs, cellular or gene therapies that are able to achieve similar or better results. We may face competition with respect to any product candidates that we seek to develop or commercialize in the future from major pharmaceutical companies and specialty pharmaceutical companies worldwide. Potential competitors also include academic institutions, government agencies, and other public and private research organizations that conduct research, seek patent protection, and establish collaborative arrangements for research, development, manufacturing, and commercialization.

There are a number of pharmaceutical and biotech companies that are currently pursuing the development of products for the treatment of the neurodegenerative disease indications for which we have research programs or have commenced clinical development, including PD. Companies developing therapeutics in the neurodegenerative disease area include large companies with significant financial resources, such as Biogen, Inc., Neuropore Therapies, Inc., Bristol Meyers Squibb, Roche Holdings AG, Prothena Corporation plc, Sanofi S.A., Takeda Pharmaceutical Co. Ltd., UCB, S.A., Denali Therapeutics Inc., Sun SPARC, 1st Biotherapeutics and AbbVie Inc. In addition to competition from other companies targeting neurodegenerative indications, any products we may develop may also face competition from other types of therapies using distinct treatment modalities.

Many of our current or potential competitors, either alone or with their strategic partners, have significantly greater financial resources and expertise in research and clinical development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals, and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Our commercial opportunities could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient, or are less expensive than any products that we may develop. Furthermore, currently approved products could be discovered to have application for treatment of the same disease indications as our product candidates, which could give such products significant regulatory and market timing advantages over any of our product candidates. Our competitors also may obtain FDA, EMA or other regulatory approval for their products more rapidly than we may obtain approval for ours and may obtain orphan product exclusivity from the FDA for indications our product candidates are targeting, which could result in our competitors establishing a strong market position before we are able to enter the market. Additionally, products or technologies developed by our competitors may render our potential product candidates uneconomical or obsolete, and we may not be successful in marketing any product candidates we may develop against competitors.

In addition, we could face litigation or other proceedings with respect to the scope, ownership, validity and/ or enforceability of our patents relating to our competitors' products and our competitors may allege that our products infringe, misappropriate or otherwise violate their intellectual property. See “— Risks Related to Our Intellectual Property.” The availability of our competitors' products could limit the demand, and the price we are able to charge, for any products that we may develop and commercialize.

The manufacture of our product candidates is complex and difficulties may be encountered in production. If such difficulties are encountered or failure to meet regulatory standards occurs, our ability to provide supply of our product candidates for clinical trials or our products for patients, if approved, could be delayed or stopped, or we may be unable to maintain a commercially viable cost structure.

The processes involved in manufacturing our drug product candidates are complex, expensive, highly- regulated and subject to multiple risks. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects and other supply disruptions. Further, as product candidates are developed through preclinical studies to potential future clinical trials towards approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods, are altered along the way in an effort to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives, and any of these changes could cause our product candidates to perform differently and affect the results of our current and planned clinical trials or other future clinical trials. We expect to rely on third-party manufacturers for the manufacturing of our products.

In order to conduct our current and planned or future clinical trials of our product candidates, or supply commercial products, if approved, we will need to have them manufactured in small and large quantities. Our manufacturing partners may be unable to successfully increase the manufacturing capacity for any of our product candidates in a timely or cost-effective manner, or at all. In addition, quality issues may arise during scale-up activities. If our manufacturing partners are unable to successfully scale up the manufacture of our product candidates in sufficient quality and quantity, the development, testing and clinical trials of that product candidate may be delayed or become infeasible, and regulatory approval or commercial launch of any resulting product may be delayed or not obtained, which could significantly harm our business. The same risks would apply to our internal manufacturing facilities, should we in the future decide to build internal manufacturing capacity. In addition, building internal manufacturing capacity would carry significant risks in terms of being able to plan, design and execute on a complex project to build manufacturing facilities in a timely and cost-efficient manner.

In addition, the manufacturing process for any products that we may develop is subject to the FDA, EMA and foreign regulatory authority approval processes and continuous oversight, and we will need to contract with manufacturers who can meet all applicable FDA, EMA and foreign regulatory authority requirements, including complying with current good manufacturing processes, or on an ongoing basis. If we or our third-party manufacturers are unable to reliably produce products to specifications acceptable to the FDA, EMA or other regulatory authorities, we may not obtain or maintain the approvals we need to commercialize such products. Even if we obtain regulatory approval for any of our product candidates, there is no assurance that either we or our CMOs will be able to manufacture the approved product to specifications acceptable to the FDA, EMA or other regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the product, or to meet potential future demand. Any of these challenges could delay completion of clinical trials, require bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidate, impair commercialization efforts, increase our cost of goods, and have an adverse effect on our business, prospects, financial condition, results of operations and growth prospects.

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

We do not have a sales or marketing infrastructure, nor have we sold, marketed, or distributed pharmaceutical products. To achieve commercial success for any approved product for which we retain sales and marketing responsibilities, we must either develop a sales and marketing organization or outsource these functions to third parties. In the future, we may choose to build a sales, marketing, and commercial support infrastructure to sell, or participate in sales activities with our collaborators for, some of our product candidates if and when they are approved.

There are risks involved with both establishing our own commercial capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force or reimbursement specialists is expensive and time consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing and other commercialization capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our commercialization personnel.

Factors that may inhibit our efforts to commercialize any approved product on our own include:

- our inability to recruit and retain adequate numbers of effective sales, marketing, reimbursement, customer service, medical affairs, and other support personnel;
- the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe any future approved products;
- the inability of reimbursement professionals to negotiate arrangements for formulary access, reimbursement, and other acceptance by payors;
- the inability to price our products at a sufficient price point to ensure an adequate and attractive level of profitability;
- restricted or closed distribution channels that make it difficult to distribute our products to segments of the patient population;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent commercialization organization.

If we enter into arrangements with third parties to perform sales, marketing, commercial support, and distribution services, our product revenue or the profitability of product revenue may be lower than if we were to market and sell any products we may develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to commercialize our product candidates or may be unable to do so on terms that are favorable to us. We may have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we do not establish commercialization capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates if approved.

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

The commercial success of any of our product candidates will depend upon its degree of market acceptance by physicians, patients, third-party payors, and others in the medical community. Even if any product candidates we may develop receive marketing approval, they may nonetheless fail to gain sufficient market acceptance by physicians, patients, healthcare payors, and others in the medical community. The degree of market acceptance of any product candidates we may develop, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy and safety of such product candidates as demonstrated in pivotal clinical trials and published in peer-reviewed journals;
- the potential and perceived advantages compared to alternative treatments;
- the ability to offer our products for sale at competitive prices;
- the ability to offer appropriate patient access programs, such as co-pay assistance;

- the extent to which physicians recommend our products to their patients;
- convenience and ease of dosing and administration compared to alternative treatments;
- the clinical indications for which the product candidate is approved by the FDA, EMA or other comparable foreign regulatory agencies;
- product labeling or product insert requirements of the FDA, EMA or other comparable foreign regulatory authorities, including any limitations, contraindications or warnings contained in a product's approved labeling;
- restrictions on how the product is distributed;
- the timing of market introduction of competitive products;
- publicity concerning our products or competing products and treatments;
- the effectiveness of marketing and distribution efforts by us and other licensees and distributors;
- sufficient governmental third-party coverage or reimbursement; and
- the prevalence and severity of any side effects.

If any product candidates we develop do not achieve an adequate level of acceptance by physicians, healthcare payors, patients and the medical community, we will not be able to generate significant revenue, and we may not become or remain profitable. The failure of any of our product candidates to find market acceptance would harm our business prospects.

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

The regulations that govern marketing approvals, pricing, and reimbursement for new drugs vary widely from country to country. In the United States, continual legislative changes may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenue we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if any product candidates we may develop obtain marketing approval.

Our ability to successfully commercialize any products that we may develop also will depend in part on the extent to which reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers, and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Government authorities currently impose mandatory discounts for certain patient groups, such as Medicare, Medicaid and Veterans Affairs, or VA, hospitals, and may seek to increase such discounts at any time. Future regulation may negatively impact the price of our products, if they are approved for commercial sale. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any product candidate that we commercialize and, if reimbursement is available, of the level of reimbursement. Reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. In order to get reimbursement, physicians may need to show that patients have superior treatment outcomes with our products compared to standard of care drugs, including lower-priced generic versions of standard of care drugs. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval. In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors and coverage and reimbursement levels for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time consuming and costly process that may require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

There may be significant delays in obtaining reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the medicine is approved by the FDA, EMA or other comparable foreign regulatory authorities. Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale, and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. Our inability to promptly obtain coverage and profitable payment rates from both government-funded and private payors for any approved products we may develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize product candidates, and our overall financial condition.

If any of our product candidates obtain regulatory approval, additional competitors could enter the market with generic versions of such drugs, which may result in a material decline in sales of affected products.

Under the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act, a pharmaceutical manufacturer may file an ANDA, seeking approval of a generic copy of an approved, small molecule innovator product. Under the Hatch-Waxman Act, a manufacturer may also submit an NDA under section 505(b)(2) that references the FDA's prior approval of the small molecule innovator product. A 505(b)(2) NDA product may be for a new or improved version of the original innovator product. The Hatch-Waxman Act also provides for certain periods of regulatory exclusivity, which preclude FDA approval (or in some circumstances, FDA filing and reviewing) of an ANDA or 505(b)(2)NDA. These include, subject to certain exceptions, the period during which an FDA-approved drug is subject to orphan drug exclusivity. In addition to the benefits of regulatory exclusivity, an innovator NDA holder may have patents claiming the active ingredient, product formulation or an approved use of the drug, which would be listed with the product in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations," known as the "Orange Book." If there are patents listed in the Orange Book, a generic or 505(b)(2) applicant that seeks to market its product before expiration of the patents must include in the ANDA a "Paragraph IV certification," challenging the validity or enforceability of, or claiming non-infringement of, the listed patent or patents. Notice of the certification must be given to the innovator, too, and if within 45 days of receiving notice the innovators use to protect its patents, approval of the ANDA is stayed for 30 months, or as lengthened or shortened by the court.

Accordingly, if any of our product candidates are approved, competitors could file ANDAs for generic versions of our drug products or 505(b)(2) NDAs that reference our drug products, respectively. If there are patents listed for our drug products in the Orange Book, those ANDAs and 505(b)(2) NDAs would be required to include a certification as to each listed patent indicating whether the ANDA applicant does or does not intend to challenge the patent. We cannot predict which, if any, patents in our current portfolio or patents we may obtain in the future will be eligible for listing in the Orange Book, how any generic competitor would address such patents, whether we would sue on any such patents, or the outcome of any such suit.

We may not be successful in securing or maintaining proprietary patent protection for products and technologies we develop or license. Moreover, if any of our owned or in-licensed patents that are listed in the Orange Book are successfully challenged by way of a Paragraph IV certification and subsequent litigation, the affected product could immediately face generic competition and its sales would likely decline rapidly and materially. Should sales decline, we may have to write off a portion or all of the intangible assets associated with the affected product and our results of operations and cash flows could be materially and adversely affected. See "— Risks Related to Our Intellectual Property."

Conducting any clinical trials of our product candidates and any future commercial sales of a product candidate may expose us to expensive product liability claims, and we may not be able to maintain product liability insurance on reasonable terms or at all and may be required to limit commercialization of our product candidates.

We face an inherent risk of product liability as a result of the preclinical and clinical testing of our product candidates and will face an even greater risk when and if we commercialize any products. For example, we may be sued if our product candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during preclinical or clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit testing and commercialization of our product candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased or interrupted demand for our products;
- injury to our reputation;
- withdrawal of clinical trial participants and inability to continue our clinical trials;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- exhaustion of any available insurance and our capital resources;
- the inability to commercialize any product candidate; and
- a decline in the price of our Common Stock.

Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop, alone or with collaborators. Our insurance policies may have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Even if our agreements with any future corporate collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise.

Risks Related to Regulatory Approval and Other Legal Compliance Matters

The regulatory approval processes of the FDA, EMA and comparable foreign regulatory authorities are lengthy, time consuming, and inherently unpredictable. If we are ultimately unable to obtain regulatory approval for our product candidates, we will be unable to generate product revenue and our business will be substantially harmed.

The time required to obtain approval by the FDA, EMA and comparable foreign regulatory authorities is unpredictable, typically takes many years following the commencement of clinical trials, and depends upon numerous factors, including the type, complexity and novelty of the product candidates involved. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions, which may cause delays in the approval or the decision not to approve an application. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application, may disagree with our regulatory strategy or proposed pathway for approval or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. We have not submitted for, or obtained regulatory approval for any product candidate, and it is possible that none of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval.

Applications for our product candidates could fail to receive regulatory approval for many reasons, including, but not limited to the following:

- the FDA, EMA or comparable foreign regulatory authorities may disagree with the design, implementation or results of our preclinical or clinical trials;
- the FDA, EMA or comparable foreign regulatory authorities may determine that our product candidates are not safe and effective, only moderately effective or have undesirable or unintended side effects, toxicities or other characteristics that preclude our obtaining marketing approval or prevent or limit commercial use;
- the population studied in the clinical program may not be sufficiently broad or representative to assure efficacy and safety in the full population for which we seek approval;
- we may be unable to demonstrate to the FDA or comparable foreign regulatory authorities that a product candidate's risk-benefit ratio when compared to the standard of care is acceptable;
- the data collected from preclinical or clinical trials of our product candidates may not be sufficient to support the submission of an NDA, or other submission or to obtain regulatory approval in the United States or elsewhere;
- we may be unable to demonstrate to the FDA, EMA or comparable foreign regulatory authorities that a product candidate's risk-benefit ratio for its proposed indication is acceptable;
- the FDA, EMA or comparable foreign regulatory authorities may fail to approve the manufacturing processes, test procedures and specifications, or facilities of third-party manufacturers with which we contract for preclinical, clinical and commercial supplies; and
- the approval policies or regulations of the FDA, EMA or comparable foreign regulatory authorities may significantly change in a manner rendering our preclinical or clinical data insufficient for approval.

This lengthy approval process, as well as the unpredictability of the results of clinical trials, may result in our failing to obtain regulatory approval to market any of our product candidates, which would significantly harm our business, results of operations, and prospects.

If the FDA does not conclude that certain of our product candidates satisfy the requirements for the Section 505(b)(2) regulatory approval pathway, or if the requirements for such product candidates under Section 505(b)(2) are not as we expect, the approval pathway for those product candidates will likely take significantly longer, cost significantly more and entail significantly greater complications and risks than anticipated, and in either case may not be successful.

We plan to seek FDA approval through the Section 505(b)(2) regulatory pathway for IkT-001Pro. The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, added Section 505(b)(2) to the FDCA. Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference. Section 505(b)(2), if applicable to us under the FDCA, would allow an NDA we submit to the FDA to rely in part on data in the public domain or the FDA's prior conclusions regarding the safety and effectiveness of approved compounds, which could expedite the development program for our product candidates by potentially decreasing the amount of clinical data that we would need to generate in order to obtain FDA approval.

On January 19, 2024, members of the Company along with its medical oncology consultants met with the FDA Review Team (the "Review Team") from the Division of Hematologic Malignancies in a Pre-NDA meeting to discuss our bioequivalence studies of IkT-001Pro and its path to approval. All questions were addressed and summarized in official meeting minutes issued by the FDA on February 12, 2024. During the meeting we inquired whether additional clinical studies may be needed to seek approval and discussed manufacturing and quality control requirements for approval. The Review Team acknowledged that the 505(b)(2) pathway appears to be the appropriate pathway for approval of IkT-001Pro and indicated that, pending formal review of our clinical data, clinical studies completed to date indicate that 600 mg and 800 mg IkT-001Pro provides similar exposures to 400 mg and 600 mg imatinib mesylate, respectively, subject to review of the NDA upon filing. In addition, given that imatinib mesylate is approved for use between 300 mg and 800 mg once daily for a variety of blood and gastrointestinal cancers, the Review Team stated that if we intend to seek approval across all currently approved indications, we should evaluate additional dose(s) as needed to measure the safety, tolerability and bioequivalent dose of IkT-001Pro that would deliver up to 800 mg, the highest approved dose of imatinib mesylate. The Review Team also discussed the possible difference between IkT-001Pro and imatinib mesylate absorption in the gut and recommended that we evaluate whether IkT-001Pro and imatinib mesylate behave differently with respect to certain gut transporters that regulate absorption. We are in alignment with the FDA and are initiating the necessary pre-clinical test to evaluate this further to ensure that delivery of imatinib by IkT-001Pro mimics imatinib mesylate in all respects. Finally, a number of recommendations were discussed to prevent the

potential mix-up between 001Pro and imatinib mesylate either at the pharmacy or by patients for two drugs delivering the same active ingredient. We discussed alternate dosage forms for IkT-001Pro relative to imatinib mesylate as the primary mitigation strategy and will provide a justification of the dosage forms chosen and why they are unlikely to cause medication errors. To ensure that we meet the manufacturing requirements for approval, we will request milestone-based meetings with the Review Team as we complete the required manufacturing and quality control processes.

If the FDA does not approve the NDA under the Section 505(b)(2) regulatory pathway as anticipated, we may need to conduct additional clinical trials, provide additional data and information, and meet additional standards for regulatory approval. If this were to occur, the time and financial resources required to obtain FDA approval for these product candidates, and complications and risks associated with these product candidates, would likely substantially increase. We could need to obtain more additional funding, which could result in significant dilution to the ownership interests of our then existing stockholders to the extent we issue equity securities or convertible debt. We cannot assure you that we would be able to obtain such additional financing on terms acceptable to us, if at all. Moreover, inability to pursue the Section 505(b)(2) regulatory pathway would likely result in new competitive products reaching the market more quickly than our product candidates, which would likely materially adversely impact our competitive position and prospects. Even if we are allowed to pursue the Section 505(b)(2) regulatory pathway, we cannot assure you that our product candidates will receive the requisite approvals for commercialization.

In addition, notwithstanding the approval of a number of products by the FDA under Section 505(b)(2) over the last few years, certain brand-name pharmaceutical companies and others have objected to the FDA's interpretation of Section 505(b)(2). If the FDA's interpretation of Section 505(b)(2) is successfully challenged, the FDA may change its Section 505(b)(2) policies and practices, which could delay or even prevent the FDA from approving any NDA that we submit under Section 505(b)(2). The pharmaceutical industry is highly competitive, and Section 505(b)(2) NDAs are subject to special requirements designed to protect the patent rights of sponsors of previously approved drugs that are referenced in a Section 505(b)(2) NDA. These requirements may give rise to patent litigation and mandatory delays in approval of our NDAs for up to 30 months or longer depending on the outcome of any litigation. It is not uncommon for a manufacturer of an approved product to file a citizen petition with the FDA seeking to delay approval of, or impose additional approval requirements for, pending competing products. If successful, such petitions can significantly delay, or even prevent, the approval of the new product. However, even if the FDA ultimately denies such a petition, the FDA may substantially delay approval while it considers and responds to the petition. In addition, even if we are able to utilize the Section 505(b)(2) regulatory pathway, there is no guarantee this would ultimately lead to faster product development or earlier approval.

Moreover, even if our product candidates are approved under Section 505(b)(2), the approval may be subject to limitations on the indicated uses for which the products may be marketed or to other conditions of approval, or may contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the products.

If we file a Section 505(b)(2) application that references a product marketed by another manufacturer, we may be subject to a patent infringement suit and the approval of our product may be delayed.

If we file a Section 505(b)(2) application that relies in whole or in part on studies conducted by a third-party, we will be required to certify to the FDA that either: (1) there is no patent information listed in the FDA's publication *Approved Drug Products with Therapeutic Equivalence Evaluations*, which we refer to as the Orange Book, with respect to the third-party NDA for the applicable approved drug candidate; (2) the patents listed in the Orange Book have expired; (3) the listed patents have not expired, but will expire on a particular date and approval is sought after patent expiration; or (4) the listed patents are invalid or will not be infringed by the manufacture, use or sale of our drug. A certification that our new drug will not infringe the Orange Book-listed patents for the applicable approved drug candidate, or that such patents are invalid, is called a paragraph IV certification. If we submit a paragraph IV certification to the FDA, a notice of the paragraph IV certification must also be sent to the NDA holder once our Section 505(b)(2) application is accepted for filing by the FDA. The third-party may then initiate a lawsuit to defend the patents identified in the notice. The filing of a patent infringement lawsuit within 45 days of receipt of the notice automatically prevents the FDA from approving the Section 505(b)(2) application until the earliest of 30 months or the date on which the patent expires, the lawsuit is settled, or the court reaches a decision in the infringement lawsuit in favor of us.

The third-party may file a patent infringement lawsuit outside the 45-day period, in which case, our Section 505(b)(2) application will not be subject to the 30-month stay of FDA approval.

Our product candidates may cause undesirable side effects or have other properties that could halt their clinical development, prevent their regulatory approval, limit their commercial potential, or result in significant negative consequences.

Adverse events or other undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay, or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA, EMA or other comparable foreign regulatory authorities. Drug-related side effects could affect patient recruitment, the ability of enrolled patients to complete the study, and/or result in potential product liability claims. We are required to maintain product liability insurance pursuant to our business practice. We may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. A successful product liability claim or series of claims brought against us could cause our stock price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations, prospects, and business. In addition, regardless of merit or eventual outcome, product liability claims may result in impairment of our business reputation, withdrawal of clinical trial participants, costs due to related litigation, distraction of management's attention from our primary business, initiation of investigations by regulators, substantial monetary awards to patients or other claimants, the inability to commercialize our product candidates, and decreased demand for our product candidates, if approved for commercial sale.

Additionally, if one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects or adverse events caused by such products, a number of potentially significant negative consequences could result, including, but not limited to:

- regulatory authorities may withdraw approvals of such product or impose restrictions on distribution;
- regulatory authorities may require additional warnings or contraindications on the label that could diminish the usage or otherwise limit the commercial success of the product;
- we may be required to change the way the product is administered or conduct additional clinical trials or post-approval studies;
- we may be forced to suspend marketing of the product;
- we may be required to create a REMS plan, which could include a medication guide outlining the risks of such side effects for distribution to patients, a communication plan for healthcare providers, and/or other elements to assure safe use;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could significantly harm our business, results of operations, and prospects.

We may conduct future clinical trials for our product candidates outside the United States, and the FDA, EMA and applicable foreign regulatory authorities may not accept data from such trials.

We may in the future choose to conduct one or more clinical trials outside the United States, including in Europe. The acceptance of study data from clinical trials conducted outside the United States or another jurisdiction by the FDA, EMA or applicable foreign regulatory authority may be subject to certain conditions. In cases where data from foreign clinical trials are intended to serve as the basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the United States population and United States medical practice; and (ii) the trials were performed by clinical investigators of recognized competence and pursuant to cGCP regulations. Additionally, the FDA's clinical trial requirements, including sufficient size of patient populations and statistical significance, must be met. Many foreign regulatory bodies have similar approval requirements. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA, EMA or any applicable foreign regulatory authority will accept data from trials conducted outside of the United States or the applicable jurisdiction. If the FDA, EMA or any applicable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which would be costly and time-consuming and delay aspects of our business plan, and which may result in our product candidates not receiving approval or clearance for commercialization in the applicable jurisdiction, and could significantly harm our business, prospects, financial condition, and results of operations.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our product candidates in other jurisdictions.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, but a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA or EMA grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion of the product candidate for those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from those in the United States, including additional preclinical studies or clinical trials as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we or any partner we work with fail to comply with the regulatory requirements in international markets or fail to receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed.

Even if we obtain regulatory approval for a product candidate, our products will remain subject to extensive regulatory scrutiny.

If any of our product candidates are approved, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies, and submission of safety, efficacy, and other post-market information, including both federal and state requirements in the United States and requirements of comparable foreign regulatory authorities.

Manufacturers and manufacturers' facilities are required to comply with extensive requirements imposed by the FDA, EMA and comparable foreign regulatory authorities, including ensuring that quality control and manufacturing procedures conform to cGMP regulations. As such, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any NDA, biologics license application to the FDA, or BLA or marketing authorization application, or MAA. Accordingly, we and others with whom we work must continue to expend time, money, and effort in all areas of regulatory compliance, including manufacturing, production and quality control.

Any regulatory approvals that we receive for our product candidates will be subject to limitations on the approved indicated uses for which the product may be marketed and promoted or to the conditions of approval (including the requirement to implement a REMS), or contain requirements for potentially costly post-marketing testing. We will be required to report certain adverse reactions and production problems, if any, to the FDA, EMA and comparable foreign regulatory authorities. Any new legislation addressing drug safety issues could result in delays in product development or commercialization, or increased costs to assure compliance. The FDA and other agencies, including the Department of Justice, closely regulate and monitor the post-approval marketing and promotion of products to ensure that they are manufactured, marketed and distributed only for the approved indications and in accordance with the provisions of the approved labeling. We will have to comply with requirements concerning advertising and promotion for our products. Promotional communications with respect to prescription drugs are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved label. As such, we may not promote our products for indications or uses for which they do not have approval. The holder of an approved NDA, BLA, or MAA must submit new or supplemental applications and obtain approval for certain changes to the approved product, product labeling, or manufacturing process. We could also be asked to conduct post-marketing clinical trials to verify the safety and efficacy of our products in general or in specific patient subsets. If original marketing approval was obtained via the accelerated approval pathway, we could be required to conduct a successful post-marketing clinical trial to confirm clinical benefit for our products. An unsuccessful post-marketing study or failure to complete such a study could result in the withdrawal of marketing approval.

If a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, or disagrees with the promotion, marketing or labeling of a product, such regulatory agency may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If we, our product candidates or the manufacturing facilities for our product candidates fail to comply with applicable regulatory requirements, a regulatory agency or enforcement authority may, among other things:

- issue warning letters that would result in adverse publicity;
- impose civil or criminal penalties;

- suspend or withdraw regulatory approvals;
- suspend any of our ongoing clinical trials;
- refuse to approve pending applications or supplements to approved applications submitted by us;
- impose restrictions on our operations, including closing our contract manufacturers' facilities;
- mandate modifications to promotional materials or require us to provide corrective information to healthcare practitioners;
- refuse to allow us to enter into government contracts;
- seize or detain products, refuse to permit the import or export of products; or
- require a product recall.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response, and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenue from our products. If regulatory sanctions are applied or if regulatory approval is withdrawn, the value of our company and our operating results will be adversely affected.

In addition, the FDA's regulations, policies or guidance may change and new or additional statutes or government regulations in the United States and other jurisdictions may be enacted that could further restrict or regulate post-approval activities. We cannot predict the likelihood, nature or extent of adverse government regulation that may arise from pending or future legislation or administrative action, either in the United States or abroad. If we are not able to achieve and maintain regulatory compliance, we may not be permitted to market our products and/or product candidates, which would adversely affect our ability to generate revenue and achieve or maintain profitability.

Although we have received orphan drug designation for IkT-001Pro and may seek orphan drug designation for other product candidates, we may be unable to maintain the benefits associated with orphan drug designation, including market exclusivity, for IkT-001Pro, and may be unable to obtain such a designation for other product candidates. This may cause our revenue, if any, to be reduced.

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition, defined as a disease or condition with a patient population of fewer than 200,000 in the United States, or a patient population greater than 200,000 in the United States when there is no reasonable expectation that the cost of developing and making available the drug or biologic in the United States will be recovered from sales in the United States for that drug or biologic. Orphan drug designation must be requested before submitting an NDA or BLA. In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages, and user-fee waivers. After the FDA grants orphan drug designation, the generic identity of the drug and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

If a product that has orphan drug designation subsequently receives the first FDA approval for a particular active ingredient for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other NDA or BLA applications to market the same drug or biologic for the same indication for seven years, except in limited circumstances such as a showing of clinical superiority to the product with orphan exclusivity or if the FDA finds that the holder of the orphan exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan product to meet the needs of patients with the disease or condition for which the drug was designated. As a result, even if one of our product candidates receives orphan exclusivity, the FDA can still approve other drugs that have a different active ingredient for use in treating the same indication or disease. Furthermore, the FDA can waive orphan exclusivity if we are unable to manufacture sufficient supply of our product. If we lose orphan drug designation in the future for IkT-001Pro the development costs may outweigh the economic benefits from FDA approval, if any, and commercialization.

Although we intend to seek a breakthrough therapy designation for Risvodetinib (IkT-148009) and may seek a breakthrough therapy designation for other product candidates in the future, we might not receive such designation, and even if we do, such designation may not lead to a faster development of any product candidate or approval process for any product candidate.

We intend to seek a breakthrough therapy designation for Risvodetinib (IkT-148009) in one or more indications or for other product candidates. A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For drugs and biologics that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Drugs designated as breakthrough therapies by the FDA may also be eligible for priority review if supported by clinical data at the time the NDA is submitted to the FDA.

Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe that one of our product candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. Even if we receive breakthrough therapy designation, the receipt of such designation for a product candidate may not result in a faster development of any product candidate or approval process for product candidate. In addition, even if one or more of our product candidates qualify as breakthrough therapies, the FDA may later decide that the product candidates no longer meet the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. In particular, the Food and Drug Omnibus Reform Act, or “FDORA” enacted in the Consolidated Appropriations Act on December 29, 2022, further directs FDA to specify conditions for post-approval studies for products approved under accelerated approval that may provide additional requirements and timelines for conducting such studies. FDORA also directs FDA to develop procedures for withdrawing a product’s accelerated approval on an expedited basis, which may also impact one or more of our products, if we are no longer able to continue to meet the requirements for accelerated approval.

Healthcare legislative measures aimed at reducing healthcare costs may have a material adverse effect on our business and results of operations.

The United States and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system that may affect our ability to profitably sell our product and product candidates, if approved. The United States government, state legislatures and foreign governments also have shown significant interest in implementing cost-containment programs to limit the growth of government-paid healthcare costs, including price controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs.

The Affordable Care Act was intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms.

There have been significant ongoing judicial, administrative, executive and legislative efforts to modify or eliminate the Affordable Care Act since its enactment. For example, the Tax Act enacted on December 22, 2017, repealed the shared responsibility payment for individuals who fail to maintain minimum essential coverage under section 5000A of the Internal Revenue Code, commonly referred to as the individual mandate.

The Affordable Care Act has also been subject to challenges in the courts. On December 14, 2018, a Texas U.S. District Court Judge ruled that the Affordable Care Act is unconstitutional in its entirety because the “individual mandate” was repealed by Congress. On December 18, 2019, the Fifth Circuit U.S. Court of Appeals held that the individual mandate is unconstitutional and remanded the case to the Texas District Court to reconsider its earlier invalidation of the entire Affordable Care Act. An appeal was taken to the U.S. Supreme Court which upheld the Affordable Care Act in June of 2021. There have been no significant judicial challenges since then.

The Biden Administration has been supportive of all aspects of the Affordable Care Act. Further changes to and under the Affordable Care Act remain possible. For example, the Biden Administration took additional steps to lower health care costs by requiring health insurance issuers, employer-based health plans, and other group health plans to report on prescription drug and health coverage costs. The rule is the fourth rule in a series that implement the No Surprises Act and transparency requirements of the Consolidated Appropriations Act (CAA), 2021. It is unknown precisely what form any such changes or any law would take, and how or whether it may affect our business in the future. We expect that changes or additions to the Affordable Care Act, the Medicare and Medicaid programs, changes allowing the federal government to directly negotiate drug prices and changes stemming from other healthcare reform measures, especially with regard to healthcare access, financing or other legislation in individual states, could have a material adverse effect on the healthcare industry.

We expect that the Affordable Care Act, as well as other healthcare reform measures such as the Transparency Act, that have and may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for our product and product candidates, if approved, and could seriously harm our future revenues. Any reduction in reimbursement from Medicare, Medicaid, or other government programs may result in a similar reduction in payments from private payers. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain and maintain profitability of our product and product candidates, if approved.

Our employees, independent contractors, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements.

We are exposed to the risk of fraud, misconduct or other illegal activity by our employees, independent contractors, consultants, commercial partners and vendors. Misconduct by these parties could include intentional, reckless and negligent conduct that fails to:

- comply with the laws of the FDA, EMA and other comparable foreign regulatory authorities;
- provide true, complete and accurate information to the FDA, EMA and other comparable foreign regulatory authorities;
- comply with manufacturing standards we have established;
- comply with healthcare fraud and abuse laws in the United States and similar foreign fraudulent misconduct laws; or
- report financial information or data accurately or to disclose unauthorized activities to us.

If we obtain FDA approval of any of our product candidates and begin commercializing those products in the United States, our potential exposure under such laws will increase significantly, and our costs associated with compliance with such laws are also likely to increase. In particular, research, sales, marketing, education and other business arrangements in the healthcare industry are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, educating, marketing and promotion, sales and commission, certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. We have adopted a code of business conduct and ethics, but it is not always possible to identify and deter misconduct by employees and third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

If we fail to comply with healthcare laws, we could face substantial penalties and our business, operations and financial conditions could be adversely affected.

Healthcare providers, physicians and payors play a primary role in the recommendation and prescription of any product candidates for which we may obtain marketing approval. Our future arrangements with payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute any product candidates for which we may obtain marketing approval. Even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payors, federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to our business. Restrictions under applicable federal, state and foreign healthcare laws and regulations may affect our ability to operate and expose us to areas of risk, including:

- federal civil and criminal false claims laws and civil monetary penalty laws, including the False Claims Act, which impose criminal and civil penalties, including through civil "qui tam" or "whistleblower" actions, against individuals or entities from knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid, or other third-party payors that are false or fraudulent or knowingly making a false statement to improperly avoid, decrease or conceal an obligation to pay money to the federal government. A person or entity does not need to have actual knowledge of these statutes or specific intent to violate them in order to have committed a violation;
- HIPAA, which created federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, which impose requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization;
- the federal Physician Payments Sunshine Act, created under the ACA, and its implementing regulations, which require manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health Insurance Program to report annually to the U.S. Department of Health and Human Services under the Open Payments Program, information related to payments or other transfers of value made to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members, as well as other state and foreign laws regulating marketing activities;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and
- analogous state and foreign laws and regulations, such as state and foreign anti-kickback, false claims, consumer protection and unfair competition laws which may apply to pharmaceutical business practices, including, but not limited to, research, distribution, sales and marketing arrangements as well as submitting claims involving healthcare items or services reimbursed by any third-party payer, including commercial insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry’s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government that otherwise restricts payments that may be made to healthcare providers and other potential referral sources; state laws that require drug manufacturers to file reports with states regarding pricing and marketing information, such as the tracking and reporting of gifts, compensations and other remuneration and items of value provided to healthcare professionals and entities; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could, despite our efforts to comply, be subject to challenge under one or more of such laws. Efforts to ensure that our business arrangements will comply with applicable healthcare laws may involve substantial costs. It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations. In addition, the approval and commercialization of any of our product candidates outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

If we or any contract manufacturers and suppliers we engage fail to comply with environmental, health, and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We and any contract manufacturers and suppliers we currently or may in the future engage are subject to numerous federal, state, and local environmental, health, and safety laws, regulations, and permitting requirements, including those governing laboratory procedures; the generation, handling, use, storage, treatment, and disposal of hazardous and regulated materials and wastes; the emission and discharge of hazardous materials into the ground, air, and water; and employee health and safety. Our operations involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. Under certain environmental laws, we could be held responsible for costs relating to any contamination at our current or past facilities and at third-party facilities. We also could incur significant costs associated with civil or criminal fines and penalties.

Compliance with applicable environmental laws and regulations may be expensive, and current or future environmental laws and regulations may impair our research, product development and manufacturing efforts. In addition, we cannot entirely eliminate the risk of accidental injury or contamination from these materials or wastes. Although we maintain workers' compensation insurance to cover us for costs and expenses, we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not carry specific biological or hazardous waste insurance coverage, and our property, casualty, and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and our preclinical trials, future clinical trials or regulatory approvals could be suspended, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Risks Related to Our Reliance on Third Parties

We currently rely on and expect to continue to rely on third parties to conduct our clinical trials and preclinical testing, as well as future research and clinical trials, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials, research, or testing.

We currently rely and expect to continue to rely on third parties, such as CROs, clinical data management organizations, medical institutions, and clinical investigators, to conduct our research, preclinical testing and clinical research and current clinical trial and will rely on such third parties to conduct any future clinical trials. Any of these third parties may terminate their engagements with us or be unable to fulfill their contractual obligations. If we need to enter into alternative arrangements, it will delay our product development activities.

Our reliance on these third parties for research and development activities reduces our control over these activities but does not relieve us of our responsibilities. For example, we remain responsible for ensuring that any current or future clinical trials would be conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with cGCPs for conducting, recording, and reporting the results of any current or future clinical trials to assure that data and reported results are credible, reproducible and accurate and that the rights, integrity, and confidentiality of trial participants are protected. We also are required to register any current or future clinical trials and post the results of completed clinical trials on a government-sponsored database within certain time frames. Failure to do so can result in fines, adverse publicity, and civil and criminal sanctions.

Our CROs are not our employees, and except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our ongoing preclinical programs and any future clinical trials. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the preclinical or clinical data they obtain is compromised due to the failure to adhere to our preclinical or future clinical protocols, regulatory requirements or for other reasons, our preclinical and any future clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, the commercial prospects for our product candidates would be harmed, our costs could increase substantially and our ability to generate revenue could be delayed.

Switching or adding additional CROs involves additional cost and requires management time and focus. Identifying, qualifying and managing performance of third-party service providers can be difficult, time-consuming and cause delays in our development programs. In addition, there is a natural transition period when a new CRO commences work and the new CRO may not provide the same type or level of services as the original provider. If any of our relationships with our CROs terminate, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms. As a result, delays may occur, which can materially impact our ability to meet our desired clinical development timelines.

Additionally, if these third parties do not successfully carry out their contractual duties, meet expected deadlines, or conduct our preclinical or any current or future clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for any product candidates we may develop and will not be able to, or may be delayed in our efforts to, successfully commercialize our medicines.

We also expect to rely on other third parties to store and distribute drug supplies for any current or future clinical trials. Any performance failure on the part of our distributors could delay future clinical development or marketing approval of any product candidates we may develop or commercialization of our medicines, producing additional losses and depriving us of potential product revenue.

We expect to depend in whole or in part on collaborations with third parties for the research, development and commercialization of any product candidates we may develop. If any such collaborations are not successful, we may not be able to realize the market potential of those product candidates.

We expect to work with third-party collaborators in whole or in part for the development and commercialization of any product candidates we may develop. Our collaborators may include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies and academic institutions and commercial research organizations. If we enter into any such arrangements with any third parties, we will likely have shared or limited control over the amount and timing of resources that our collaborators dedicate to the development or potential commercialization of any product candidates we may seek to develop with them. Our ability to generate revenue from these arrangements with commercial entities will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements. We cannot predict the success of any collaboration that we enter into.

Such collaborations pose the following risks to us:

- collaborators generally have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not properly obtain, maintain, enforce, or defend intellectual property or proprietary rights relating to our product candidates or research programs or may use our proprietary information in such a way as to expose us to potential litigation or other intellectual property related proceedings, including proceedings challenging the scope, ownership, validity and enforceability of our intellectual property;
- we may need the cooperation of our collaborators to enforce or defend any intellectual property we contribute to or that arises out of our collaborations, which may not be provided to us;
- disputes may arise between the collaborators and us that result in the delay or termination of the research, development, or commercialization of our product candidates or research programs or that result in costly litigation or arbitration that diverts management attention and resources;
- collaborators may decide to not pursue development and commercialization of any product candidates we develop or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborator's strategic focus or available funding or external factors such as an acquisition that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials, or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates or research programs if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- collaborators with marketing and distribution rights to one or more product candidates may not commit sufficient resources to the marketing and distribution of such product candidates;
- we may lose certain valuable rights under circumstances identified in our collaborations; collaborators may undergo a change of control and the new owners may decide to take the collaboration in a direction which is not in our best interest;
- collaborators may become bankrupt, which may significantly delay our research or development programs, or may cause us to lose access to valuable technology, know-how or intellectual property of the collaborator relating to our products, product candidates or research programs;
- key personnel at our collaborators may leave, which could negatively impact our ability to productively work with our collaborators; collaborations may require us to incur short- and long-term expenditures or issue securities that dilute our stockholders or disrupt our management and business; collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates; and
- collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all. If a present or future collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our development or commercialization program under such collaboration could be delayed, diminished, or terminated.

We may face significant competition in seeking appropriate collaborations. Recent business combinations among biotechnology and pharmaceutical companies have resulted in a reduction of potential collaborators. In addition, the negotiation process is time-consuming and complex, and we may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of the product candidate for which we are seeking to collaborate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop product candidates or bring them to market and generate product revenue.

If we enter into collaborations to develop and potentially commercialize any product candidates, we may not be able to realize the benefit of such transactions if we or our collaborator elect not to exercise the rights granted under the agreement or if we or our collaborator are unable to successfully integrate a product candidate into existing operations. In addition, if our agreement with any of our collaborators terminates, our access to technology and intellectual property licensed to us by that collaborator may be restricted or terminate entirely, which may delay our continued development of our product candidates utilizing the collaborator's technology or intellectual property or require us to stop development of those product candidates completely. We may also find it more difficult to find a suitable replacement collaborator or attract new collaborators, and our development programs may be delayed or the perception of us in the business and financial communities could be adversely affected. Many of the risks relating to product development, regulatory approval, and commercialization described in this "Risk Factors" section also apply to the activities of our collaborators and any negative impact on our collaborators may adversely affect us.

We contract with third parties for the manufacture of materials for our research programs, preclinical studies and current clinical trial and expect to continue to do so for any future clinical trials and for commercialization of any product candidates that we may develop. This reliance on third parties carries and may increase the risk that we will not have sufficient quantities of such materials or product candidates that we may develop and commercialize, or that such supply will not be available to us at an acceptable cost, which could delay, prevent, or impair our development or commercialization efforts.

We do not currently have any manufacturing facilities. We currently rely on third-party manufacturers for the manufacture of our materials for preclinical studies and current clinical trial and expect to continue to do so, including for any future clinical trials, unless we choose to establish our own manufacturing facilities for preclinical studies, any current and future clinical trials and for commercial supply of any product candidates that we may develop.

We may be unable to establish any further agreements with third-party manufacturers or to do so on acceptable terms. Even if we are able to establish agreements with third-party manufacturers, reliance on third party manufacturers entails additional risks, including:

- the possible breach of the manufacturing agreement by the third-party;
- the possible termination or non-renewal of the agreement by the third-party at a time that is costly or inconvenient for us;
- reliance on the third-party for regulatory compliance, quality assurance, safety, and pharmacovigilance and related reporting; and
- the inability to produce required volume in a timely manner and to quality standards.

Third-party manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements outside the United States. Our third-party manufacturers may have little or no experience manufacturing materials that we require for our preclinical studies and current and future clinical trials. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in clinical holds on our trials, sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocations, seizures or recalls of product candidates, operating restrictions, and criminal prosecutions, any of which could significantly and adversely affect our business, financial condition, results of operations, and prospects.

Any product candidates that we may develop may compete with other product candidates and products for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us.

Any performance failure on the part of our existing or future manufacturers could delay any future clinical development or marketing approval. We do not currently have arrangements in place for redundant supply for any of our product candidates. If any one of our current contract manufacturers cannot perform as agreed, we may be required to replace that manufacturer and may incur added costs and delays in identifying and qualifying any such replacement. Furthermore, securing and reserving production capacity with contract manufacturers may result in significant costs.

Our current and anticipated future dependence upon others for the manufacture of any product candidates we may develop may adversely affect our future profit margins and our ability to commercialize any product candidates that receive marketing approval on a timely and competitive basis.

Manufacturing issues may arise that could increase product and regulatory approval costs or delay commercialization.

As we scale up manufacturing of our product candidates and conduct required stability testing, we may encounter product, packaging, equipment and process-related issues that may require refinement or resolution in order to proceed with any current or future clinical trials and obtain regulatory approval for commercial marketing. In the future, we may identify impurities, which could result in increased scrutiny by regulatory authorities, delays in our clinical programs and regulatory approval, increases in our operating expenses, or failure to obtain or maintain approval for our product candidates.

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

We rely on third-party suppliers for the raw materials required for the production of our product candidates. Our dependence on these third-party suppliers and the challenges we may face in obtaining adequate supplies of raw materials involve several risks, including limited control over pricing, availability, quality and delivery schedules. As a small company, our negotiation leverage is limited and we are likely to get lower priority than our competitors who are larger than we are. We cannot be certain that our suppliers will continue to provide us with the quantities of these raw materials that we require or satisfy our anticipated specifications and quality requirements. Any supply interruption in limited or sole source raw materials could materially harm the ability to manufacture our product candidates until a new source of supply, if any, could be identified and qualified. We may be unable to find a sufficient alternative supply channel in a reasonable time or on commercially reasonable terms. Any performance failure on the part of our suppliers could delay the development and potential commercialization of our product candidates, including limiting supplies necessary for future clinical trials and regulatory approvals, which would have a material adverse effect on our business.

We currently rely on a small number of suppliers for manufacturing our product candidates.

We currently rely on a small number of chemical manufacturers for our product candidates. If our suppliers were to have their businesses disrupted either inside or outside of the United States, we might be unable to find a replacement for such source in a timely manner, if at all. If a manufacturer were to be acquired by a competitor, the competitor may elect not to continue to manufacture for us at all. The loss of a supplier could cause manufacturing delays given the strict licensing requirements in this industry. If for any reason we were to change any one of our third-party contract manufacturers, we could face difficulties that might adversely affect our ability to maintain an adequate supply of our products, and we would incur costs and expend resources in the course of making the change. Moreover, we might not be able to obtain terms as favorable as those received from our current third-party contract manufacturers, which in turn would increase our costs.

We are dependent on third-party manufacturers which are located in China, and any inability to obtain products from any such manufacturers could harm our business.

Many of our current and future product candidates are expected to be manufactured in whole or in part by companies that are located in China. This concentration exposes us to risks associated with doing business globally. The political, legal and cultural environment in China is rapidly evolving, and any change that impairs our ability to obtain products from manufacturers in that region could have a material adverse effect on our business, operating results and financial condition.

Political uncertainty in the United States may result in significant changes to U.S. trade policies, treaties and tariffs, potentially involving trade policies and tariffs regarding China, including the potential disallowance of tax deductions for imported merchandise or the imposition of unilateral tariffs on imported products.

These developments, or the perception that any of them could occur, may have a material adverse effect on global economic conditions and the stability of global financial markets, and may significantly reduce global trade and, in particular, trade between China and the United States. Any of these factors could depress economic activity, restrict our sourcing from suppliers and have a material adverse effect on our business, financial condition and results of operations and affect our strategy. We cannot predict whether any of the countries in which our product candidates or raw materials are currently manufactured or may be manufactured in the future will be subject to additional trade restrictions imposed by the United States and foreign governments, nor can we predict the likelihood, type or effect of any such restrictions.

Moreover, the recurrence of the COVID-19 pandemic or the rise of a new pandemic in China could impair our ability to obtain product candidates and raw materials from manufacturers in that region or to obtain products at marketable rates. Such events may result in the need for us to consider and establish relationships with manufacturers in different countries from which to source our product candidates and raw materials and could have a material adverse effect on our business, operating results and financial condition.

Risks Related to Our Intellectual Property

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

Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries for compositions of matter for each of our product candidates and any other technologies we may develop. We seek to protect our proprietary position by prosecuting intellectual property and filing patent applications in the United States and abroad relating to our product candidates, as well as other technologies that are important to our business. Given that the development of our technology and product candidates is at an early stage, our intellectual property portfolio with respect to certain aspects of our technology and product candidates is also at an early stage. We have filed patent applications on these aspects of our technology and core product candidates; however, there can be no assurance that any such patent applications will issue as granted patents. Furthermore, in some cases, we have only filed provisional patent applications on certain aspects of our technology and product candidates and each of these provisional patent applications is not eligible to become an issued patent until, among other things, we file a non-provisional patent application within 12 months of the filing date of the applicable provisional patent application. Any failure to file a non-provisional patent application within this timeline could cause us to lose the ability to obtain patent protection for the inventions disclosed in the associated provisional patent applications. Furthermore, in some cases, we may not be able to obtain issued claims covering compositions relating to our product candidates, as well as other technologies that are important to our business, and instead may need to rely on filing patent applications with claims covering a method of use and/or method of manufacture for protection of such product candidates and other technologies. There can be no assurance that any such patent applications will issue as granted patents, and even if they do issue, such patent claims may be insufficient to prevent third parties, such as our competitors, from utilizing our technology. Any failure to obtain or maintain patent protection with respect to our product candidates could have a material adverse effect on our business, financial condition, results of operations, and prospects.

If any of our owned patent applications do not issue as patents in any jurisdiction, we may not be able to compete effectively.

Changes in either the patent laws or their interpretation in the United States and other countries may diminish our ability to protect our inventions, obtain, maintain, and enforce our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our owned and licensed patents. With respect to both in-licensed and owned intellectual property, we cannot predict whether the patent applications we and our licensors are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient protection from competitors or other third parties.

The patent prosecution process is expensive, time-consuming, and complex, and we may not be able to file, prosecute, maintain, enforce, or license all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output in time to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, CROs, contract manufacturers, consultants, advisors, and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. In addition, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our inventions and the prior art allow our inventions to be patentable over the prior art. Furthermore, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we or our licensors were the first to make the inventions claimed in any of our owned or licensed patents or pending patent applications, or that we or our licensors were the first to file for patent protection of such inventions.

If the scope of any patent protection we obtain is not sufficiently broad, or if we lose any of our patent protection, our ability to prevent our competitors from commercializing similar or identical technology and product candidates would be adversely affected.

The patent position of pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability, and commercial value of our patent rights are highly uncertain. Our owned or in-licensed pending and future patent applications may not result in patents being issued which protect our product candidates or other technologies or which effectively prevent others from commercializing competitive technologies and product candidates.

Moreover, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if patent applications we license or own currently or in the future issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. Any patents that we own or in-license may be challenged, narrowed, circumvented, or invalidated by third parties. Consequently, we do not know whether our product candidates or other technologies will be protectable or remain protected by valid and enforceable patents. Our competitors or other third parties may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner which could materially adversely affect our business, prospects, financial condition, results of operations and prospects.

The issuance of a patent is not conclusive as to its inventorship, scope, validity, or enforceability, and our patents may be challenged in the courts or patent offices in the United States and abroad. We or our licensors may be subject to a third-party pre-issuance submission of prior art to the USPTO, or become involved in opposition, derivation, revocation, reexamination, post-grant and *inter partes* review, or interference proceedings or other similar proceedings challenging our owned or licensed patent rights. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate or render unenforceable, our owned or in-licensed patent rights, allow third parties to commercialize our product candidates or other technologies and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. Moreover, we, or one of our licensors, may have to participate in interference proceedings declared by the USPTO to determine priority of invention or in post-grant challenge proceedings, such as oppositions in a foreign patent office, that challenge our or our licensor's priority of invention or other features of patentability with respect to our owned or in-licensed patents and patent applications. Such challenges may result in loss of patent rights, loss of exclusivity, or in patent claims being narrowed, invalidated, or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our product candidates and other technologies. Such proceedings also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us.

In addition, given the amount of time required for the development, testing, and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

Some of our owned and in-licensed patents and patent applications are, and may in the future be, co-owned with third parties. For example, we co-own certain patents and patent applications relating to our pro drug technology to be applied to protein kinase inhibitors for oncology and non-oncology indications that was jointly developed with Sphaera. Our exclusive rights to certain of these patents and patent applications are dependent, in part, on operating agreements between the joint owners of such patents and patent applications. If our licensors or co-owners fail to sustain the grant of exclusive licenses to us or we are otherwise unable to maintain such exclusive rights, our licensors or co-owners may be able to license these rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of our licensors and co-owners in order to enforce such patents against third parties, and such cooperation may not be provided to us. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

If we fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business.

We have entered into license agreements with third parties and may need to obtain additional licenses from others to advance our research or allow commercialization of product candidates. It is possible that we may be unable to obtain additional licenses at a reasonable cost or on reasonable terms, if at all. In that event, we may be required to expend significant time and resources to redesign our technology, product candidates, or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected product candidates, which could harm our business, financial condition, results of operations, and prospects significantly. We cannot provide any assurances that third-party patents do not exist which might be enforced against our current technology, manufacturing methods, product candidates, or future methods or products resulting in either an injunction prohibiting our manufacture or future sales, or, with respect to our future sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties, which could be significant.

In addition, each of our license agreements, and we expect our future agreements, will impose various development, diligence, commercialization, and other obligations on us. Certain of our license agreements also require us to meet development timelines, or to exercise commercially reasonable efforts to develop and commercialize licensed products, in order to maintain the licenses. In spite of our efforts, our licensors might conclude that we have materially breached our obligations under such license agreements and might therefore terminate the license agreements, thereby removing or limiting our ability to develop and commercialize products and technology covered by these license agreements. If these in-licenses are terminated, or if the underlying patents fail to provide the intended exclusivity, competitors or other third parties would have the freedom to seek regulatory approval of, and to market, products identical to ours and we may be required to cease our development and commercialization of certain of our product candidates. Any of the foregoing could have a material adverse effect on our competitive position, business, prospects, financial conditions, results of operations, and prospects.

Moreover, disputes may arise regarding intellectual property subject to a licensing agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights under our collaborative development relationships;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

In addition, the agreements under which we currently license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, prospects, financial condition and results of operations. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could have a material adverse effect on our business, prospects, financial conditions and results of operations.

We may not be able to protect our intellectual property and proprietary rights throughout the world.

Filing, prosecuting, and defending patents on our product candidates and other technologies in all countries throughout the world would be prohibitively expensive, and the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection but enforcement is not as strong as that in the United States. These products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets, and other intellectual property protection, particularly those relating to pharmaceutical products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our intellectual property and proprietary rights generally. Proceedings to enforce our intellectual property and proprietary rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our licensors are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and this may have material adverse effects on our business, prospects, financial condition and results of operations.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment, and other requirements imposed by government patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees, and various other government fees on patents and applications will be due to be paid to the USPTO and various government patent agencies outside of the United States over the lifetime of our owned or licensed patents and applications. In certain circumstances, we rely on our licensing partners to pay these fees due to U.S. and non-U.S. patent agencies. The USPTO and various non-U.S. government agencies require compliance with several procedural, documentary, fee payment, and other similar provisions during the patent application process. We are also dependent on our licensors to take the necessary action to comply with these requirements with respect to our licensed intellectual property. In some cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in a partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market with similar or identical products or technology, which could have a material adverse effect on our business, prospects, financial condition and results of operations.

Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our products.

Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. Assuming that other requirements for patentability are met, prior to March 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. After March 2013, under the Leahy-Smith America Invents Act, or the America Invents Act, enacted in September 2011, the United States transitioned to a first inventor to file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third-party was the first to invent the claimed invention. A third-party that files a patent application in the USPTO after March 2013, but before us, could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third-party. This will require us to be cognizant going forward of the time from invention to filing of a patent application. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we or our licensors were the first to either (i) file any patent application related to our product candidates or other technologies or (ii) invent any of the inventions claimed in our or our licensor's patents or patent applications.

The America Invents Act also includes a number of significant changes that affect the way patent applications will be prosecuted and also may affect patent litigation. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, inter partes review, and derivation proceedings. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third-party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third-party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third-party as a defendant in a district court action. Therefore, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our owned or in-licensed patent applications and the enforcement or defense of our owned or in-licensed issued patents, all of which could have a material adverse effect on our business, prospects, financial condition and results of operations.

In addition, the patent positions of companies in the development and commercialization of pharmaceuticals are particularly uncertain. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. This combination of events has created uncertainty with respect to the validity and enforceability of patents, once obtained. Depending on future actions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our existing patent portfolio and our ability to protect and enforce our intellectual property in the future.

Issued patents covering our product candidates and other technologies could be found invalid or unenforceable if challenged in court or before administrative bodies in the United States or abroad.

If we or one of our licensors initiated legal proceedings against a third-party to enforce a patent covering our product candidates or other technologies, the defendant could counterclaim that such patent is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Third parties may raise claims challenging the validity or enforceability of our owned or in-licensed patents before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post-grant review, inter partes review, interference proceedings, derivation proceedings, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in the revocation of, cancellation of, or amendment to our patents in such a way that they no longer cover product candidates or other technologies. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we or our licensing partners and the patent examiner were unaware during prosecution. If a third-party were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our product candidates or other technologies. Such a loss of patent protection would have a material adverse impact on our business, prospects, financial condition and results of operations.

If we do not obtain patent term extension and data exclusivity for any product candidates we may develop, our business may be materially harmed.

Depending upon the timing, duration and specifics of any FDA marketing approval of any product candidates we may develop, one or more of our owned or in-licensed U.S. patents may be eligible for limited patent term extension under the Hatch-Waxman Act. The Hatch-Waxman Act permits a patent term extension of up to five years as compensation for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. Similar extensions as compensation for patent term lost during regulatory review processes are also available in certain foreign countries and territories, such as in Europe under a Supplementary Patent Certificate. However, we may not be granted an extension in the United States and/or foreign countries and territories because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is shorter than what we request, our competitors may obtain approval of competing products following our patent expiration, and could have a material adverse effect on our business, prospects, financial condition and results of operations.

We may be subject to claims challenging the inventorship of our patents and other intellectual property.

We or our licensors may be subject to claims that former employees, collaborators or other third parties have an interest in our owned or in-licensed patents, trade secrets, or other intellectual property as an inventor or co-inventor. For example, we or our licensors may have inventorship disputes arise from conflicting obligations of employees, consultants or others who are involved in developing our product candidates or other technologies. Litigation may be necessary to defend against these and other claims challenging inventorship or our licensors' ownership of our owned or in-licensed patents, trade secrets or other intellectual property. If we or our licensors fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property that is important to our product candidates and other technologies. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Any of the foregoing could have a material adverse effect on our business, prospects, financial condition and results of operations.

Some intellectual property may have been discovered through government funded programs and thus may be subject to federal regulations such as "march-in" rights, certain reporting requirements and a preference for U.S.-based companies. Compliance with such regulations may limit our exclusive rights, and limit our ability to contract with non-U.S. manufacturers.

All of our novel and in-licensed compounds were funded in whole or in part by the U.S. government, and are therefore subject to certain federal regulations. When new technologies are developed with U.S. government funding, the U.S. government generally obtains certain rights in any resulting patents, including a non-exclusive license authorizing the U.S. government to use the invention or to have others use the invention on its behalf, commonly referred to as march-in rights. The U.S. government's rights may also permit it to disclose the funded inventions and technology to third parties and to exercise march-in rights to use or allow third parties to use the technology we have licensed that was developed using U.S. government funding. The U.S. government may exercise its march-in rights if it determines that action is necessary because we fail to achieve practical application of the government-funded technology, or because action is necessary to alleviate health or safety needs, to meet requirements of federal regulations, or to give preference to U.S. industry. In addition, our rights in such inventions may be subject to certain requirements to manufacture products embodying such inventions in the United States in certain circumstances and if this requirement is not waived. Any exercise by the U.S. government of such rights or by any third-party of its reserved rights could have a material adverse effect on our business, prospects, financial condition, and results of operations.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to seeking patents for our product candidates and other technologies, we also rely on trade secrets and confidentiality agreements to protect our unpatented know-how, technology, and other proprietary information and to maintain our competitive position. Trade secrets and know-how can be difficult to protect. We expect our trade secrets and know-how to over time be disseminated within the industry through independent development, the publication of journal articles describing the methodology, and the movement of personnel from academic to industry scientific positions. In addition, because we may collaborate with various collaborators on the development and commercialization of one or more of our product candidates and because we may rely on third parties to manufacture our product candidates, we may be required, at times, to share trade secrets with them prior to disclosing proprietary information. We seek to protect these trade secrets and other proprietary technology, in part, by entering into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements or other similar agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, CROs, contract manufacturers, consultants, advisors, and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants as well as train our employees not to bring or use proprietary information or technology from former employers to us or in their work, and remind former employees when they leave their employment of their confidentiality obligations. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. We cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary technology and processes. Despite our efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive, and time-consuming, and the outcome is unpredictable.

In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third-party, we would have no right to prevent them from using that technology or information to compete with us. Given that our proprietary position is based, in part, on our know-how and trade secrets, if any of our trade secrets were to be disclosed to or independently developed by a competitor or other third-party, our competitive position would be materially and adversely harmed, and may have an adverse effect on our business.

In addition, these agreements typically restrict the ability of our advisors, employees, third-party contractors and consultants to publish data potentially relating to our trade secrets, although our agreements may contain certain limited publication rights. For example, any academic institution that we may collaborate with may be granted rights to publish data arising out of such collaboration, provided that we are notified in advance and given the opportunity to delay publication for a limited time period in order for us to secure patent protection of intellectual property rights arising from the collaboration, in addition to the opportunity to remove confidential or trade secret information from any such publication. Our existing collaborative research and development programs may require us to share trade secrets under the terms of our research and development collaborations or similar agreements. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of our agreements with third parties, independent development or publication of information by any of our third-party collaborators. A competitor's discovery of our trade secrets would impair our competitive position and have an adverse impact on our business.

We may be subject to claims that our employees, consultants, or advisors have wrongfully used or disclosed alleged trade secrets of their current or former employers or claims asserting ownership of what we regard as our own intellectual property.

Many of our employees, consultants, and advisors are currently or were previously employed at universities or other pharmaceutical companies, which may include competitors and potential competitors. Although we try to ensure that our employees, consultants, and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these individuals have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

In addition, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could have a material adverse effect on our business, prospects, financial condition and results of operations.

Third-party claims of intellectual property infringement, misappropriation or other violation against us, our licensors or our collaborators may prevent or delay the development and commercialization of our product candidates and other technologies.

The field of discovering treatments for our target indications is highly competitive and dynamic. Due to the research and development that is taking place in this field, the intellectual property landscape is in flux, and it may remain uncertain in the future. As such, there may be significant intellectual property related litigation and proceedings relating to our owned and in-licensed, and other third-party, intellectual property and proprietary rights in the future.

Our commercial success depends in part on our, our licensors' and our collaborators' ability to avoid infringing, misappropriating and otherwise violating the patents and other intellectual property rights of third parties. There is a substantial amount of complex litigation involving patents and other intellectual property rights in the pharmaceutical industry, as well as administrative proceedings for challenging patents, including interference, derivation and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. As discussed above, recently, due to changes in U.S. law referred to as patent reform, new procedures including inter partes review and post-grant review have been implemented. As stated above, this reform adds uncertainty to the possibility of challenge to our patents in the future.

Numerous U.S. and foreign issued patents and pending patent applications owned by third parties exist relating to the fields in which we are developing our product candidates. As the pharmaceutical industry expands and more patents are issued, the risk increases that our product candidates and other technologies may give rise to claims of infringement of the patent rights of others. We cannot assure you that our product candidates and other technologies that we have developed, are developing or may develop in the future will not infringe existing or future patents owned by third parties. We may not be aware of patents that have already been issued and that a third-party, for example, a competitor in the fields in which we are developing our product candidates, and other technologies might assert are infringed by our current or future product candidates or other technologies, including claims to compositions, formulations, methods of manufacture or methods of use or treatment that cover product candidates or other technologies. It is also possible that patents owned by third parties of which we are aware, but which we do not believe are relevant to our product candidates or other technologies, could be found to be infringed by our product candidates or other technologies. In addition, because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that our product candidates or other technologies may infringe.

Third parties may have patents or obtain patents in the future and claim that the manufacture, use or sale of our product candidates or other technologies infringes upon these patents. In the event that any third-party claims that we infringe their patents or that we are otherwise employing their proprietary technology without authorization and initiates litigation against us, even if we believe such claims are without merit, a court of competent jurisdiction could hold that such patents are valid, enforceable and infringed by our product candidates or other technologies. In this case, the holders of such patents may be able to block our ability to commercialize the applicable product candidate or technology unless we obtain a license under the applicable patents, or until such patents expire or are finally determined to be held invalid or unenforceable. Such a license may not be available on commercially reasonable terms or at all. Even if we are able to obtain a license, the license would likely obligate us to pay license fees or royalties or both, and the rights granted to us might be nonexclusive, which could result in our competitors gaining access to the same intellectual property. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, we may be unable to commercialize our product candidates or other technologies, or such commercialization efforts may be significantly delayed, which could in turn significantly harm our business.

Defense of infringement claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of management and other employee resources from our business, and may impact our reputation. In the event of a successful claim of infringement against us, we may be enjoined from further developing or commercializing our infringing product candidates or other technologies. In addition, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties and/or redesign our infringing product candidates or technologies, which may be impossible or require substantial time and monetary expenditure. In that event, we would be unable to further develop and commercialize our product candidates or other technologies, which could harm our business significantly.

Engaging in litigation to defend against third parties alleging that we have infringed, misappropriated or otherwise violated their patents or other intellectual property rights is very expensive, particularly for a company of our size, and time-consuming. Some of our competitors may be able to sustain the costs of litigation or administrative proceedings more effectively than we can because of greater financial resources. Patent litigation and other proceedings may also absorb significant management time. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings against us could impair our ability to compete in the marketplace. The occurrence of any of the foregoing could have a material adverse effect on our business, prospects, financial condition or results of operations.

We may become involved in lawsuits to protect or enforce our patents and other intellectual property rights, which could be expensive, time consuming, and unsuccessful.

Competitors may infringe our patents or the patents of our licensing partners, or we may be required to defend against claims of infringement. In addition, our patents or the patents of our licensing partners also may become involved in inventorship, priority or validity disputes. To counter or defend against such claims can be expensive and time consuming. In an infringement proceeding, a court may decide that a patent owned or in-licensed by us is invalid or unenforceable, the other party's use of our patented technology falls under the safe harbor to patent infringement under 35 U.S.C. §271(e)(1), or may refuse to stop the other party from using the technology at issue on the grounds that our owned and in-licensed patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our owned or in-licensed patents at risk of being invalidated or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions, or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing, or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

We use Inhibikase Therapeutics, the Inhibikase Therapeutics logo, and other marks to represent us in the United States and other countries. We have applied to federally register our primary trademarks in our primary market, the United States. Three of the four trademark applications that we filed for (INHIBIKASE, IKT (and Design) and RAMP) have issued to registration, and the fourth application (a second application for INHIBIKASE) is allowed and is currently awaiting registration by the United States Patent and Trademark Office. We have applied to register INHIBIKASE in Australia, Canada, the EU, Japan, Switzerland and the UK. Five of the six foreign trademark applications that we filed for have issued to registration, and the sixth application is currently awaiting registration by the Canada Patent and Trademark Office. In sum, other than the three U.S. federal registrations noted above and the registrations in the ex-US territories listed above, we have not secured trademark protection for any of our trademarks or trade names in any of our other geographic markets, and failure to secure those registrations could adversely affect our business. Our unregistered trademarks and trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other third-party marks. Indeed, it is unclear what enforceable rights, if any, we presently own in these marks or names outside of the United States. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other trademarks which are prior to our trademarks or trade names, and which are confusingly similar to our marks or names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our business, prospects, financial condition and results of operations.

Intellectual property rights do not necessarily address all potential threats.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to make products that are similar to our product candidates or utilize similar technology but that are not covered by the claims of the patents that we license or may own;
- we, or our current or future licensors or collaborators, might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our owned or licensed trade secret rights;
- it is possible that our current or future pending owned or licensed patent applications will not lead to issued patents;
- issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors or other third parties;
- our competitors or other third parties might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets, provided those products do not infringe any patents we own or license in these markets;
- we may not develop additional proprietary technologies that are patentable;
- we might not be able to protect our trademarks and/or trade names;
- the patents of others may harm our business; and
- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third-party may subsequently file a patent covering such intellectual property.

Should any of these events occur, they could have a material adverse effect on our business, prospects, financial condition and results of operations.

Risks Related to Our Operations

We will need to grow the size and capabilities of our organization, and we may experience difficulties in managing this growth.

As of the date of this Report, we had eight full-time employees, one part-time employee and five contractors to oversee critical activities and perform services on our behalf. Due to our limited employee headcount and dependence on contractors, we have operated with our employees and contractors conducting most of their activities outside of our offices. In addition, historically we have limited our cash compensation expenses. After our initial public offering in December 2020, and again in March 2022, the cash compensation of our chief executive officer and our chief financial officer increased as described in the Section titled “Executive Compensation,” and our cash compensation expense for employees and consultants also increased.

As our development plans and strategies develop, and as we operate as a public company, we must add a significant number of additional managerial, operational, financial, and other personnel, as well as expand our facilities. Future growth will impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, retaining, and motivating additional employees and consultants;
- identifying and leasing suitable corporate, development and/or research facilities;
- managing our internal development efforts effectively, including the clinical and FDA review process for our current and future product candidates, while complying with our contractual obligations to contractors and other third parties; expanding our operational, financial and management controls, reporting systems, and procedures; and
- managing increasing operational and managerial complexity.

Our future financial performance and our ability to continue to develop and, if approved, commercialize our product candidates will depend, in part, on our ability to effectively manage any future growth. Our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to manage these growth activities. Our ability to successfully manage our expected growth is uncertain given the fact that only one of our executive officers has been a full-time employee since our incorporation in June 2010. This lack of full-time experience working together as a company may adversely impact our senior management team's ability to effectively manage our business and growth.

We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors and consultants to provide certain services. These independent organizations, advisors and consultants may be employed by entities other than us, and may have commitments that limit their time, resources and availability to perform services for us. There can be no assurance that the services of these independent organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements if necessary. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by consultants is compromised for any reason, our clinical trials may be extended, delayed, or terminated, and we may not be able to obtain regulatory approval of our product candidates or otherwise advance our business. There can be no assurance that we will be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, if at all.

If we are not able to effectively expand our organization by hiring new employees and expanding our set of service providers, we may not be able to successfully implement the tasks necessary to further develop our product candidates and, accordingly, may not achieve our research, development, and commercialization goals.

We are highly dependent on our key personnel, and if we are not successful in attracting, motivating and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.

Our ability to compete in the highly competitive pharmaceutical industries depends upon our ability to attract, motivate and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on our management, particularly on our Chief Executive Officer, Dr. Werner, and our scientific and medical contract employees and future personnel, including our board of directors and scientific advisory board, many of whom have significant experience in drug development and marketing, and who could prove hard to replace. The loss of the services provided by any of our executive officers, key employees and consultants, or other scientific and medical advisors, and our inability to find suitable replacements, could result in delays in the development of our product candidates and harm our business.

As previously announced on January 16, 2024, on March 31, 2024, Mr. Frattaroli will step down from his role as Chief Financial Officer, and Garth Lees-Rolfé, our Vice President of Finance, is expected to take over this role. While we expect to engage in an orderly transition process if and when we integrate newly appointed officers and managers, we face a variety of risks and uncertainties relating to management transition, including diversion of management attention from business concerns, failure to retain other key personnel, or loss of institutional knowledge.

We conduct our operations in Atlanta, Georgia and Lexington, Massachusetts, both regions that are headquarters to many other pharmaceutical companies and many academic and research institutions. Competition for skilled personnel is intense and the turnover rate can be high, which may limit our ability to hire and retain highly qualified personnel on acceptable terms or at all. Our consultants and advisors may be engaged or employed by entities other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. We expect that we may need to recruit talent from outside of our regions, and doing so may be costly and difficult.

To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have provided and will continue to provide stock option grants that vest over time and performance stock if performance conditions are met. In the future we may grant restricted stock units. The value to employees of these equity grants that vest over time may be significantly affected by movements in our stock price that are beyond our control, and may at any time be insufficient to counteract more lucrative offers from other companies. Although we have employment agreements with our key employees, these employment agreements, other than for Dr. Werner, provide for at-will employment, which means that any of our employees could leave our employment at any time, with or without notice. We maintain a "key man" insurance policy on the life of Dr. Werner. If we are unable to attract and incentivize quality personnel on acceptable terms, or at all, it may cause our business and operating results to suffer.

Cybersecurity breaches could expose us to liability, damage our reputation, compromise our confidential information or otherwise adversely affect our business.

We maintain sensitive company data on our computer networks, including our intellectual property and proprietary business information, as well as certain information regarding our product candidates and clinical trials. We face a number of threats to our

networks from unauthorized access, security breaches and other system disruptions. Despite our security measures, our infrastructure may be vulnerable to attacks by hackers or other disruptive problems. Any such security breach may compromise information stored on our networks and may result in significant data losses or theft of our intellectual property, proprietary business information or our customers' personally identifiable information. A cybersecurity breach could hurt our reputation by adversely affecting the perception of customers and potential customers of the security of their orders and personal information. In addition, a cybersecurity attack could result in other negative consequences, including disruption of our internal operations, increased cybersecurity protection costs, lost revenues or litigation.

Our computer systems, or those used by our third-party research institution collaborators, CROs or other contractors or consultants, may fail or suffer security breaches.

Despite the implementation of security measures, our internal computer systems and those of our future CROs and other contractors and consultants may be vulnerable to damage from computer viruses and unauthorized access. Although to our knowledge we have not experienced any such material system failure or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed, ongoing or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on our third-party research institution collaborators for research and development of our product candidates and other third parties for the manufacture of our product candidates and to conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or systems, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of our product candidates could be delayed.

Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.

Our operations, and those of our third-party research institution collaborators, CROs, CMOs, suppliers, and other contractors and consultants, could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical pandemics such as COVID-19, and other natural or man-made disasters or business interruptions, for which we may not be insured. In addition, we rely on our third-party research institution collaborators for conducting research and development of our product candidates, and they may be affected by government shutdowns or withdrawn funding. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. We rely on third-party manufacturers to produce and process our product candidates. Our ability to obtain clinical supplies of our product candidates could be disrupted if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption. Damage or extended periods of interruption to our facilities due to fire, natural disaster, power loss, communications failure, unauthorized entry or other events could cause us to cease or delay development of some or all of our product candidates.

Our ability to use our net operating loss carry forwards and certain other tax attributes may be limited.

As of December 31, 2023, federal net operating loss carryforwards of approximately \$1.6 million which will begin to expire in varying amounts annually beginning in 2030 and \$33.1 million of federal net operating losses with no expiration. At December 31, 2023, the Company had state net operating loss carryforwards of approximately \$30.2 million which will begin to expire in varying amounts annually beginning in 2030. These net operating loss carry forwards could expire unused and be unavailable to offset future income tax liabilities. Additionally, under current federal income tax law, federal net operating loss incurred in tax years beginning after December 31, 2017 may be carried forward indefinitely, but the deductibility of such federal net operating loss generally is limited to 80% of U.S. federal taxable income.

The Tax Cuts and Jobs Act (TCJA) resulted in significant changes to the treatment of research and developmental (R&D) expenditures under Section 174. For tax years beginning after Dec. 31, 2021, taxpayers are required to capitalize and amortize all R&D expenditures that are paid or incurred in connection with their trade or business. Specifically, costs for U.S.-based R&D activities must be amortized over five years and costs for foreign R&D activities must be amortized over 15 years—both using a midyear convention. During the year ended December 31, 2023, the Company capitalized for tax purposes \$12.6 million and \$0.7 million of domestic and foreign R&D expenses, respectively.

To the extent that we continue to generate taxable losses, unused losses will carry forward to offset future taxable income, if any. We may be limited in the portion of net operating loss carry forwards and other tax attributes, such as research tax credits, that we can use in the future to offset taxable income for U.S. federal and state income tax purposes. Under Sections 382 and 383 of the United States Internal Revenue Code of 1986, as amended, or the Code, and corresponding provisions of state law, if a corporation undergoes an “ownership change” (generally defined as a greater than 50-percentage-point cumulative change (by value) in the equity ownership of certain stockholders over a rolling three-year period), the corporation’s ability to use its pre-change net operating loss carry forwards and other pre-change tax attributes, such as research tax credits, to offset its post-change taxable income or taxes may be limited. We experienced ownership changes in connection with our December 2020 initial public offering and June 2021 and January 2023 follow on offerings and may do so in the future as a result of subsequent shifts in our stock ownership, some of which are outside our control. Our net operating loss carry forwards may also be subject to limitation under state laws. Further, our ability to utilize net operating loss carry forwards of companies that we may acquire in the future may also be subject to limitations. As a result, even if we attain profitability, we may be unable to use a material portion of our net operating loss and other tax attributes, such as research tax credits, which could adversely affect our future cash flows.

Risks Related to Ownership of Our Common Stock

The market price of our common stock may be volatile.

Some of the factors that may cause the market price of our common stock to fluctuate include:

- results of our preclinical studies and clinical trials, or regulatory status of our product candidates;
- results of preclinical studies, clinical trials, or regulatory approvals of product candidates of our competitors, or announcements about new research programs or product candidates of our competitors;
- delays in filing our INDs, commencing trials, or objections by the FDA as to the content of our INDs;
- failure or discontinuation of any of our product development and research programs;
- any delay of the FDA in approving, or failure to approve, the design of our planned clinical trials for our current product candidates or for any future product candidates that we may develop;
- the results of our efforts to develop additional product candidates or products; commencement or termination of collaborations for our product development and research programs; the success of existing or new competitive products or technologies;
- the level of expenses related to any of our research programs, clinical development programs, or product candidates that we may develop;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents, or other proprietary rights;
- actual or anticipated changes in estimates as to financial results, development timelines, or recommendations by securities analysts;
- announcement or expectation of additional financing efforts;
- sales of our common stock by us, our insiders, or other stockholders;
- expiration of lock-up agreements;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in estimates or recommendations by securities analysts, if any, that cover our stock;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical sector; and
- general economic, industry, and market conditions.

In recent years, the stock market in general, and the market for pharmaceutical companies in particular, has experienced significant price and volume fluctuations that have often been unrelated or disproportionate to changes in the operating performance of the companies whose stock is experiencing those price and volume fluctuations. Broad market and industry factors may seriously affect the market price of our common stock, regardless of our actual operating performance. Following periods of such volatility in the market price of a company's securities, securities class action litigation has often been brought against that company. Because of the potential volatility of our stock price, we may become the target of securities litigation in the future. Securities litigation could result in substantial costs and divert management's attention and resources from our business.

A substantial amount of our total outstanding shares are restricted from immediate resale and may be sold only under the limitations of Rule 144 under the Securities Act of 1933 or pursuant to a future registration statement. The sale of such shares could cause the market price of our common stock to decline significantly, even if our business is doing well.

A substantial number of shares held by our directors, executive officers and other affiliates will continue to be subject to certain limitations of Rule 144 under the Securities Act of 1933, as amended, or the Securities Act. However, such limitations may be reduced or removed in the future, if for example such shares are subsequently registered pursuant to the Securities Act. Sales of a substantial number of shares of our common stock in the public market could occur at any time. If such sales occur, or if there is a perception that such sales will occur, the market price of our common stock could fall significantly, even if our business is doing well.

We will require additional capital in the future and raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

We will require additional capital in the future and we may seek additional capital through a combination of public and private equity offerings, debt financings, strategic partnerships and alliances and licensing arrangements. We, and indirectly, our stockholders, will bear the cost of issuing and servicing such securities. Because our decision to issue debt or equity securities in any future offering will depend on market conditions and other factors beyond our control, we cannot predict or estimate the amount, timing or nature of any future offerings. To the extent that we raise additional capital through the sale of equity or debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a stockholder. The incurrence of indebtedness would result in increased fixed payment obligations and could involve restrictive covenants, 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. If we raise additional funds through strategic partnerships and alliances and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or product candidates, or grant licenses on terms unfavorable to us.

Insiders control a significant number of shares of our common stock, which could limit your ability to affect the outcome of key transactions, including a change of control.

Our directors, executive officers, holders of more than 5% of our outstanding stock and their respective affiliates beneficially own shares representing approximately 16.8% of our outstanding common stock. As a result, these stockholders, if they act together, will be able to influence our management and affairs and all matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions. As of March 1, 2024, Dr. Werner alone beneficially owned shares representing approximately 14.6% of our outstanding common stock. This concentration of ownership may have the effect of delaying or preventing a change in control of our company and might affect the market price of our common stock.

We are an "emerging growth company" and a "smaller reporting company" and the reduced disclosure requirements applicable to emerging growth companies may make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012, as amended, or the JOBS Act. For so long as we remain an emerging growth company, we are permitted and plan to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include, but are not limited to: (i) exemption from compliance with the auditor attestation requirements pursuant to Section 404(b) of the Sarbanes-Oxley Act of 2002 ("SOX"); (ii) exemption from compliance with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements; (iii) reduced disclosure about our executive compensation arrangements; and (iv) exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We will continue to remain an emerging growth company until the earliest of the following: (i) the last day of the fiscal year following the fifth anniversary of the date of the completion of our initial public offering; (ii) the last day of the fiscal year in which our total annual gross revenue is equal to or more than \$1.07 billion; (iii) the date on which we have issued more than \$1 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC.

In addition, we are currently a “smaller reporting company,” as defined in the Securities Exchange Act of 1934, as amended, or Exchange Act, and have elected to take advantage of certain of the scaled disclosures available to smaller reporting companies. To the extent that we continue to qualify as a “smaller reporting company” as such term is defined in Rule 12b-2 under the Exchange Act, after we cease to qualify as an emerging growth company, certain of the exemptions available to us as an “emerging growth company” may continue to be available to us as a “smaller reporting company,” including exemption from compliance with the auditor attestation requirements pursuant to SOX and reduced disclosure about our executive compensation arrangements. We will continue to be a “smaller reporting company” until we have \$250 million or more in public float (based on our Common Stock) measured as of the last business day of our most recently completed second fiscal quarter or, in the event we have no public float (based on our Common Stock) or a public float (based on our Common Stock) that is less than \$700 million, annual revenues of \$100 million or more during the most recently completed fiscal year.

As a result, the information we provide stockholders will be different than the information that is available with respect to other public companies. At the time of writing this, we have not included all of the executive compensation related information that would be required if we were not an emerging growth company, nor have we included all of the quantitative and qualitative disclosures about market risk that would be required if we were not a smaller reporting company. We cannot predict whether investors will find our common stock less attractive if we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock, and our stock price may be more volatile.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have opted to take advantage of this extended transition period for the adoption of certain accounting standards.

We will incur increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives and corporate governance practices.

As a public company, and particularly after we are no longer an emerging growth company, we will incur significant legal, accounting, and other expenses that we did not incur as a private company. Section 404 of SOX, the Dodd- Frank Wall Street Reform and Consumer Protection Act, the listing requirements of Nasdaq, and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. We expect that we will need to hire additional accounting, finance, and other personnel in connection with our efforts to comply with the requirements of being a public company, and our management and other personnel will need to devote a substantial amount of time towards maintaining compliance with these requirements. These requirements will increase our legal and financial compliance costs and will make some activities more time-consuming and costly.

Pursuant to Section 404 of SOX, we will be required to furnish a report by our management on our internal control over financial reporting beginning with our second filing of an Annual Report on Form 10-K with the SEC. However, while we remain an emerging growth company or smaller reporting company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 of SOX within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants, adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented, and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed time frame or at all, that our internal control over financial reporting is effective as required by SOX. If we identify one or more material weaknesses, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

We do not expect to pay any dividends for the foreseeable future. Investors in our common stock may never obtain a return on their investment.

You should not rely on an investment in our common stock to provide dividend income. We do not anticipate that we will pay any dividends to holders of our common stock in the foreseeable future. Instead, we plan to retain any earnings to maintain and expand our existing operations. In addition, any future credit facility we enter into, or debt instrument that we issue, may contain terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock. Accordingly, investors must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any return on their investment. As a result, investors seeking cash dividends should not purchase our common stock.

Delaware law and provisions in our amended and restated certificate of incorporation and bylaws might discourage, delay, or prevent a change in control of our company or changes in our management and, therefore, depress the trading price of our common stock.

Provisions in our amended and restated certificate of incorporation and amended and restated bylaws may discourage, delay, or prevent a merger, acquisition, or other change in control that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares of our common stock. These provisions may also prevent or frustrate attempts by our stockholders to replace or remove our management. Therefore, these provisions could adversely affect the price of our common stock. Among other things, our charter documents:

- establish that our board of directors is divided into three classes, Class I, Class II and Class III, with each class serving staggered three-year terms;
- provide that vacancies on our board of directors may be filled only by a majority of directors then in office, even though less than a quorum;
- provide that our directors may only be removed for cause;
- eliminate cumulative voting;
- authorize our board of directors to issue shares of preferred stock and determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval;
- provide our board of directors with the exclusive right to elect a director to fill a vacancy or newly created directorship;
- permit stockholders to only take actions at a duly called annual or special meeting and not by written consent;
- prohibit stockholders from calling a special meeting of stockholders;
- require that stockholders give advance notice to nominate directors or submit proposals for consideration at stockholder meetings;
- authorize our board of directors, by a majority vote, to amend the bylaws; and
- require the affirmative vote of at least 66 2/3% or more of the outstanding shares of common stock to amend many of the provisions described above.

In addition, Section 203 of the General Corporation Law of the State of Delaware, or DGCL, prohibits a publicly-held Delaware corporation from engaging in a business combination with an interested stockholder, generally a person which together with its affiliates owns, or within the last three years has owned, 15% of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner.

Any provision of our amended and restated certificate of incorporation, amended and restated bylaws, or Delaware law that has the effect of delaying or preventing a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our capital stock and could also affect the price that some investors are willing to pay for our common stock.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware and the federal district courts of the United States of America will be the exclusive forums for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, or employees.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for:

- any action asserting a claim of breach of fiduciary duty;
- any action asserting a claim against us arising under the DGCL, our amended and restated certificate of incorporation, or our amended and restated bylaws; and
- any action asserting a claim against us that is governed by the internal-affairs doctrine.

The choice of the Court of Chancery of the State of Delaware as the sole and exclusive forum for any derivative action or proceeding brought on behalf of the Company shall not apply to suits seeking to enforce a duty or liability created by the Securities Act or the Exchange Act.

In addition, our amended and restated certificate of incorporation provides that the federal district courts of the United States of America shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act. There is uncertainty as to whether a court would enforce such provisions. Some companies that adopted a similar federal district court forum selection provision are currently subject to a suit in the Chancery Court of Delaware by stockholders who assert that this provision is not enforceable. If a court were to find either choice of forum provision contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business and financial condition.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

We are subject to the periodic reporting requirements of the Exchange Act. Our disclosure controls and procedures are designed to reasonably assure that information required to be disclosed by us in reports we file or submit under the Exchange Act are accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements or insufficient disclosures due to error or fraud may occur and not be detected.

General Risk Factors

If securities analysts do not publish research or reports about our business or if they publish negative evaluations of our stock, the price of our stock could decline.

The trading market for our common stock will rely in part on the research and reports that industry or financial analysts publish about us or our business. We currently are being covered by a limited number of financial analysts. If no additional analysts commence coverage of us or existing analysts cease coverage, the trading price of our stock could decrease. Even if we do obtain additional analyst coverage, if one or more of the analysts covering our business down grade their evaluations of our stock, the price of our stock could decline. If one or more of these analysts cease to cover our stock, we could lose visibility in the market for our stock, which in turn could cause our stock price to decline.

Changes in U.S. tax law could adversely affect our business and financial condition.

The laws, rules and regulations dealing with U.S. federal, state, and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect us or holders of our common stock. In recent years, many changes have been made to applicable tax laws and changes are likely to continue to occur in the future.

For example, the Tax Cuts and Jobs Act, or the TCJA, was enacted in 2017 and made significant changes to corporate taxation, including the reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, the limitation of the tax deduction for net interest expense to 30% of adjusted taxable income (except for certain small businesses), the limitation of the deduction for net operating losses from taxable years beginning after December 31, 2017 to 80% of current year taxable income and the elimination of net operating loss carry backs generated in taxable years ending after December 31, 2017 (though any such net operating losses may be carried forward indefinitely), and the modification or repeal of many business deductions and credits. The TCJA resulted in significant changes to the treatment of research and developmental (R&D) expenditures under Section 174. For tax years beginning after Dec. 31, 2021, taxpayers are required to capitalize and amortize all R&D expenditures that are paid or incurred in connection with their trade or business. Specifically, costs for U.S.-based R&D activities must be amortized over five years and costs for foreign R&D activities must be amortized over 15 years—both using a midyear convention. It cannot be predicted whether, when, in what form, or with what effective dates, new tax laws may be enacted, or regulations and rulings may be enacted, promulgated or issued under existing or new tax laws, which could result in an increase in our or our shareholders' tax liability or require changes in the manner in which we operate in order to minimize or mitigate any adverse effects of changes in tax law or in the interpretation thereof. We urge investors to consult with their legal and tax advisers regarding the implications of potential changes in tax laws on an investment in our common stock.

If we engage in acquisitions or strategic partnerships, this may increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities, and subject us to other risks.

We may engage in various acquisitions and strategic partnerships in the future, including licensing or acquiring complementary products, intellectual property rights, technologies, or businesses. Any acquisition or strategic partnership may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the potential issuance of our equity securities which would result in dilution to our stockholders;
- assimilation of operations, intellectual property, products and product candidates of an acquired company, including difficulties associated with integrating new personnel;
- the diversion of our management's attention from our existing product programs and initiatives in pursuing such an acquisition or strategic partnership;
- retention of key employees, the loss of key personnel, and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or product candidates and regulatory approvals; and
- our inability to generate revenue from acquired intellectual property, technology and/or products sufficient to meet our objectives or even to offset the associated transaction and maintenance costs.

In addition, if we undertake such a transaction, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses and acquire intangible assets that could result in significant future amortization expense.

Our business activities may be subject to the Foreign Corrupt Practices Act, or FCPA, and similar anti-bribery and anti-corruption laws.

Our business activities may be subject to the FCPA and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we operate, including the U.K. Bribery Act. The FCPA generally prohibits offering, promising, giving, or authorizing others to give anything of value, either directly or indirectly, to a non-U.S. government official in order to influence official action, or otherwise obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. Our business is heavily regulated and therefore involves significant interaction with public officials, including officials of non-U.S. governments. Additionally, in many other countries, the health care providers who prescribe pharmaceuticals are employed by their government, and the purchasers of pharmaceuticals are government entities; therefore, our dealings with these prescribers and purchasers are subject to regulation under the FCPA.

Recently, the SEC and Department of Justice have increased their FCPA enforcement activities with respect to pharmaceutical companies. There is no certainty that all of our employees, agents, contractors, or collaborators, or those of our affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws. Violations of these laws and regulations could result in fines, criminal actions against us, our officers, or our employees, the closing down of our facilities, requirements to obtain export licenses, cessation of business activities in sanctioned countries, implementation of compliance programs, and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our products in one or more countries and could materially damage our reputation, our brand, our international expansion efforts, our ability to attract and retain employees, and our business, prospects, operating results, and financial condition.

Our business is subject to economic, political, regulatory and other risks associated with conducting business internationally.

Our business is subject to risks associated with conducting business internationally because some of our suppliers and collaborative relationships are located outside the United States. Accordingly, our future results could be harmed by a variety of factors, including:

- economic weakness, including inflation, or political instability in particular non-U.S. economies and markets;
- differing and changing regulatory requirements in non-U.S. countries;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States;
- difficulties in compliance with non-U.S. laws and regulations;
- changes in non-U.S. regulations and customs, tariffs and trade barriers;
- changes in non-U.S. currency exchange rates and currency controls;
- changes in a specific country's or region's political or economic environment;
- trade protection measures, import or export licensing requirements or other restrictive actions by U.S. or non-U.S. governments;
- negative consequences from changes in tax laws;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- difficulties associated with staffing and managing international operations, including differing labor relations;
- potential liability under the FCPA or comparable foreign laws; and
- business interruptions resulting from geo-political actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods, fire and pandemics such as the ongoing global COVID-19 pandemic.

These and other risks associated with conducting business internationally may materially adversely affect our ability to attain profitable operations.

Item 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity.

Risk Management and Strategy

We recognize the importance of developing, implementing and maintaining cybersecurity measures to safeguard our information systems and protect the confidentiality, integrity, and availability of data. We have integrated cybersecurity risk management into our broader risk management framework. Our digital and technology organization outside the Company continually addresses cybersecurity risk in alignment with our business objectives and operational needs.

Our cybersecurity program is focused on the following areas:

- **Governance:** We leverage multiple cybersecurity frameworks (e.g., ISO 27001 and NIST CSF) and regulatory requirements to inform our externally managed information technology (“IT”) infrastructure. Policies for IT use and management for each employee are part of the employee onboarding process and those policies are refreshed periodically as threats emerge that could be relevant to our IT infrastructure.
- **Technical Safeguards:** The Company does not use a centralized server where all information is stored and therefore where all information is placed at risk. Instead, we deploy technical and procedural measures using a distributed model so that no one location or machine could cripple the company’s IT infrastructure. Protection measures include network firewalls, network intrusion detection and prevention, penetration testing, vulnerability assessments and monthly risk assessments and management, threat intelligence, anti-malware and access controls, plus data loss prevention and monitoring.
- **Security Awareness / Training:** All employees are required to adhere to our Standards of Business Conduct, which identifies an employee's responsibility for information security. We also disseminate security awareness information periodically throughout the year.
- **Third-Party Suppliers and Service Providers:** We manage our IT infrastructure with an external vendor who maintains and evaluates risk exposure in real-time and conducts monthly risk assessments and adjustments to preclude cyberattacks. Vendor security reviews evaluate numerous key security controls and the outputs of these reviews are used as part of business decisions regarding storage and dissemination of virtual data and to assess a vendor's overall security posture.

Risks from Cybersecurity Threats

While we are subject to ongoing cybersecurity threats, the risks from these threats have not materially affected, or are reasonably likely to materially affect the company, including our business strategy, results of operations or financial condition. For additional information regarding risks from cybersecurity threats, see "Item 1A. Risk Factors-Risks Related to Our Operations" in this Annual Report.

Board Oversight of Cybersecurity Risks

Our Board of Directors (Board) is responsible for the oversight of our risk management program and regularly reviews information regarding our most significant strategic, operational, financial, legal and compliance risks, including cybersecurity risks. The Board reviews mitigation plans through discussions with management, which includes regular Board reports and findings from management’s monthly discussions with our outside IT group. Our Board of Directors also reviews and approves our cybersecurity policies, strategies, and budgets on an annual basis.

Management's Role in Assessing and Managing Cybersecurity Risks

Our CEO in conjunction with our external IT team are responsible for setting the strategy and communicating cybersecurity risks. With the Company’s distributed model of data storage, risks have been limited and the Company has not experienced a cybersecurity breach. The Company’s security measures and monthly system audits to identify potential vulnerabilities and remediate deficiencies in real time.

Item 2. Properties.

Our corporate headquarters is located in Atlanta, Georgia, where we lease a single corporate office. Additionally, in August 2022 we opened an office, consisting of approximately 4,200 square feet, in Lexington, Massachusetts which we use as office and conference spaces for our Massachusetts based team. We have an option to extend the lease term for an additional three years thereafter. Upon opening our Lexington offices, we surrendered our lease for office space in Boston, Massachusetts. It is anticipated that these facilities will be sufficient to meet our needs for the foreseeable future.

Item 3. Legal Proceedings.

From time to time, we may become involved in litigation or other legal proceedings. We are not currently a party to any material litigation or legal proceedings. Regardless of outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Our common stock has been quoted on the Nasdaq Capital Markets under the symbol IKT since our initial public offering on December 23, 2020. Prior to that date, there was no public market for our common stock.

Holders of Record

Equiniti Trust Company, LLC (formerly known as American Stock Transfer & Trust Company, LLC) is the transfer agent for our common stock. As of March 15, 2024, there were 14 holders of record of our common stock. Not reflected in the number of stockholders of record are persons who beneficially own shares of common stock held in nominee or street name.

Dividends

The Company has never previously declared or paid any cash dividends on its common stock. We currently intend to retain earnings and profits, if any, to support our business strategy and do not intend to pay any cash dividends within the foreseeable future. Any future determination to pay cash dividends will be at the sole discretion of our Board of Directors and will depend upon the financial condition of the Company, its operating results, capital requirements, general business conditions and any other factors that our Board of Directors deems relevant.

Repurchases of Equity Securities of the Issuer

During 2023 and 2022, we did not repurchase any of our outstanding securities.

Item 6. [Reserved]

Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations.

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and the related notes to those statements included elsewhere in this Report. This discussion and analysis and other parts of this Report contain forward-looking statements based upon current beliefs, plans and expectations related to future events and our future financial performance that involve risks, uncertainties and assumptions, such as statements regarding our intentions, plans, objectives, expectations, forecasts and projections. Our actual results and the timing of selected events could differ materially from those anticipated in these forward-looking statements as a result of several factors, including those set forth under the section titled “Risk Factors” and elsewhere in this Report. You should carefully read the “Risk Factors” to gain an understanding of the important factors that could cause actual results to differ materially from our forward-looking statements. Please also see the section titled “Special Note Regarding Forward-Looking Statements.”

Overview

We are a clinical-stage pharmaceutical company developing protein kinase inhibitor therapeutics to modify the course of Parkinson’s disease (“PD”), Parkinson’s-related disorders and other diseases of the Abelson Tyrosine Kinases. The Company’s multi-therapeutic pipeline has a primary focus on neurodegeneration and its lead program utilizing Risvodetinib (also known as IkT-148009), a selective inhibitor of the non-receptor Abelson Tyrosine Kinases, targets the treatment of Parkinson’s disease inside and outside the brain as well as other diseases that arise from Abelson Tyrosine Kinases. In 2021, we commenced clinical development of Risvodetinib (IkT-148009), which we believe can modify the course of Parkinson’s disease including its manifestation in the gastrointestinal tract, or GI. In January, 2023, the Company initiated its Phase 2 program, termed ‘the 201 trial’ (www.the201trial.com), for Risvodetinib (IkT-148009) as a treatment for Parkinson’s disease and began the process of opening up to 34 sites in the U.S. As of March 22, 2024, 32 sites are open and actively evaluating prospective trial participants. 73 participants have been enrolled, 20 prospective participants are in medical screening and 48 potential participants are being evaluated for suitability to initiate medical screening. Thirty-four participants have completed the 12-week dosing period. As of March 22, 2024, 15 mild and two moderate possibly treatment-related adverse events have been reported across all enrolled patients taking Risvodetinib (IkT-148009). Depending on the timing of the last enrolled patient, results from this trial may be reported in the second half of 2024. Monthly site enrollments have increased month-over-month since our patient outreach program was initiated. As such, we believe a more rapid path to enrollment is emerging through the public outreach/awareness campaign led by the ‘the201trial.com’ website. The emerging path to complete enrollment has prompted us to take further advantage of this multi-dose study by planning to extend the 201 trial by an additional 12 months, subject to additional resources.

The twelve-week 201 trial is evaluating three doses in participants who have untreated Parkinson’s disease on a staggered schedule and will be placebo controlled with 1:1:1 randomization. The primary endpoints of this trial are safety and tolerability and a hierarchy of 15 secondary endpoints will evaluate treatment benefit in the brain and GI tract. The recent analysis of 11 patients who participated in the 201 trial prior to the temporary clinical hold issued by the U.S. Food and Drug Administration (“FDA”) in November, 2022, which was lifted in January, 2023, suggested that Risvodetinib (IkT-148009) may have some effect on disease. These participants were withdrawn from the trial following the FDA’s temporary clinical hold. As detailed at the Movement Disorder Society Congress held August 2023, the primary secondary endpoint is a functional assessment comprised of the sum of Parts 2 and 3 of the Movement Disorder Society Universal Parkinson’s Disease Rating Scale (MDS-UPDRS Parts II+III). This sum showed an average -8.7 point improvement in the three participants on the 200 mg dose relative to baseline, while three placebo participants increased by +1.7 points; this represents an average spread of -10.4 points. A lower (or negative) change relative to placebo of greater than -3 to -6 points might be considered a measure of improvement. Given the small sample size on this dose, we believe it is premature to conclude a clinical benefit, but this observation reinforces our desire to extend the trial for an additional 12 months to potentially obtain a clear picture of clinical benefit over a total measurement of 15 months.

In March 2023, we opened our IND for Risvodetinib (IkT-148009) as a treatment for the Parkinson’s-related orphan disease Multiple System Atrophy, or MSA. Our evaluation of Risvodetinib (IkT-148009) in MSA was benefited by a grant received from the National Institute of Neurological Diseases and Stroke, an Institute of the National Institutes of Health, for \$0.39 million to fund animal model studies of Risvodetinib (IkT-148009) as a therapy for MSA. Two different animal studies were undertaken to evaluate whether Risvodetinib (IkT-148009) could have an impact on disease in the animal. One model evaluated the ability of Risvodetinib (IkT-148009) to modify disease early in its progression, while the second model is evaluating whether Risvodetinib (IkT-148009) can correct functional loss much later in the disease course. The early progression model study has now been shown to preserve nearly normal functional activity following 20 weeks of once daily dosing relative to untreated controls. Preservation of function in this model occurred with substantial reduction of the underlying alpha-synuclein protein pathology. The second model evaluating Risvodetinib (IkT-148009) late in the disease course is ongoing. In addition, Risvodetinib (IkT-148009) was recently given Orphan Drug Designation by the FDA for the treatment of MSA. We plan to initiate a Phase 2 study in MSA patients in up to nineteen sites in the EU, and up to six sites in the U.S. involving at least 120 patients, and we are presently seeking non-dilutive resources to initiate and execute this trial in its entirety. The proposed Phase 2 study will have primary endpoints in safety, tolerability and efficacy

following once daily dosing at two dose levels for 12-months. We plan to submit complementary regulatory documents for Risvodetinib (IkT-148009) to European Union authorities in 2024.

We are also developing platform technologies to improve delivery of protein kinase inhibitors in patients. One example of our potential ability to improve drug delivery is IkT-001Pro, a prodrug of the anticancer agent imatinib mesylate, which is intended to treat Stable Phase Chronic Myelogenous Leukemia, or SP-CML. IkT-001Pro has completed a three-part dose finding/dose equivalence study in 66 healthy volunteers (known as ‘the 501 trial’). The study was designed to evaluate the 96-hour pharmacokinetics of imatinib delivered as IkT-001Pro and determine the dose of IkT-001Pro that can deliver the equivalent of either 400 mg or 600 mg imatinib mesylate. As of the date of this Report, bioequivalence to 400 mg imatinib mesylate has been established to our satisfaction for a 600 mg dose of IkT-001Pro. We further evaluated 600 mg imatinib mesylate and believe that a 900 mg dose of IkT-001Pro is the preferred dose of IkT-001Pro to deliver a dose of imatinib equivalent to 600 mg imatinib mesylate. We studied 800 mg IkT-001Pro and found it to be nearly equivalent to 600 mg imatinib mesylate. We intend to study a 1200 mg dose of IkT-001Pro to cover the full range of doses approved for imatinib mesylate to treat up to 11 adult and pediatric blood cancers.

On January 19, 2024, members of the Company along with its medical oncology consultants met with the FDA Review Team (the ‘Review Team’) from the Division of Hematologic Malignancies in a Pre-NDA meeting to discuss our bioequivalence studies of IkT-001Pro and its path to approval. All questions were addressed and summarized in official meeting minutes issued by the FDA on February 12, 2024. During the meeting we inquired whether additional clinical studies may be needed to seek approval and discussed manufacturing and quality control requirements for approval. The Review Team acknowledged that the 505(b)(2) pathway appears to be the appropriate pathway for approval of IkT-001Pro and indicated that, pending formal review of our clinical data, clinical studies completed to date indicate that 600 mg and 800 mg IkT-001Pro provides similar exposures to 400 mg and 600 mg imatinib mesylate, respectively, subject to review of the NDA upon filing. In addition, given that imatinib mesylate is approved for use between 300 mg and 800 mg once daily for a variety of blood and gastrointestinal cancers, the Review Team stated that if we intend to seek approval across all currently approved indications, we should evaluate additional dose(s) as needed to measure the safety, tolerability and bioequivalent dose of IkT-001Pro that would deliver up to 800 mg, the highest approved dose of imatinib mesylate. The Review Team also discussed the possible difference between IkT-001Pro and imatinib mesylate absorption in the gut and recommended that we evaluate whether IkT-001Pro and imatinib mesylate behave differently with respect to certain gut transporters that regulate absorption. We are in alignment with the FDA and are initiating the necessary pre-clinical test to evaluate this further to ensure that delivery of imatinib by IkT-001Pro mimics imatinib mesylate in all respects. Finally, a number of recommendations were discussed to prevent the potential mix-up between 001Pro and imatinib mesylate either at the pharmacy or by patients for two drugs delivering the same active ingredient. We discussed alternate dosage forms for IkT-001Pro relative to imatinib mesylate as the primary mitigation strategy and will provide a justification of the dosage forms chosen and why they are unlikely to cause medication errors. To ensure that we meet the manufacturing requirements for approval, we will request milestone-based meetings with the Review Team as we complete the required manufacturing and quality control processes.

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

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 and published those results in several high-profile peer reviewed publications. 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. We believe our approach to neurodegenerative disease is validated by our 2022 and 2023 publications and oral presentations at the major academic and industry conferences in Parkinson’s and Alzheimer’s diseases.

We currently have worldwide commercialization rights to all of our development programs and IP protection until 2033 for IkT-001Pro and 2036 for Risvodetinib (IkT-148009). Additional filings could extend this period of exclusivity longer.

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 67% and 66% of our operating expenses for the years ended December 31, 2023 and 2022, 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 IND and NDA applications with the FDA;
- our ability to conduct and commence trials;
- our ability to establish an appropriate safety profile with IND-enabling toxicology studies;
- our ability to successfully develop, obtain regulatory approval for, and then successfully commercialize, our product candidates;
- our successful enrollment in and completion of our current and future clinical trials;
- the costs associated with the development of any additional product candidates we identify in-house or acquire through collaborations;
- our ability to discover, develop and utilize biomarkers to demonstrate target engagement, pathway engagement and the impact on disease progression of our molecules;
- our ability to establish agreements with third party manufacturers for clinical supply for any future clinical trials and commercial manufacturing, if our product candidates are approved;
- the terms and timing of any collaboration, license or other arrangement, including the terms and timing of any milestone payments thereunder;
- our ability to obtain and maintain patent, trade secret and other intellectual property protection and regulatory exclusivity for our product candidates if and when approved;
- our receipt of marketing approvals from applicable regulatory authorities;

- the impact of the outbreak of the COVID-19 pandemic or other future pandemics;
- our ability to commercialize products, if and when approved, whether alone or in collaboration with others; and
- the continued acceptable safety profiles of the product candidates following approval.

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

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

	Year Ended December 31,		Change
	2023	2022	
PD	\$ 9,036,750	\$ 9,645,457	\$ (608,707)
MSA	459,193	468,016	(8,823)
CML	2,969,186	1,460,754	1,508,432
Other research and development expenses	1,153,219	460,758	692,461
Total research and development expenses	<u>\$ 13,618,348</u>	<u>\$ 12,034,985</u>	<u>\$ 1,583,363</u>

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 Lexington, Massachusetts and Atlanta, Georgia not otherwise included in research and development expenses.

We expect to incur additional expenses as a result of operating as a public 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 further 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 Years Ended December 31, 2023 and 2022

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

	Year Ended December 31,		Change	
	2023	2022	(\$)	(%)
Grant revenue	\$ 260,501	\$ 123,440	\$ 137,061	111.0
Research and development	(13,618,348)	(12,034,985)	(1,583,363)	13.2
Selling, general and administrative	(6,731,945)	(6,217,063)	(514,882)	8.3
Loss from operations	(20,089,792)	(18,128,608)	(1,961,184)	(10.8)
Interest income	1,060,909	74,453	986,456	1,324.9
Net loss	<u>\$ (19,028,883)</u>	<u>\$ (18,054,155)</u>	<u>\$ (974,728)</u>	<u>(5.4)</u>

Grant Revenue

Grant revenue for the year ended December 31, 2023 increased by \$137,061 or 111.0% to \$260,501 from \$123,440 in the prior year. The increase was driven by increased grant research activity during 2023 compared to 2022. The Company utilized its working capital and personnel resources in 2023 to carry on its Phase I and II clinical trials in addition to its grant research activity.

Research and Development

Research and development expenses increased by \$1,583,363 or 13.2% to \$13,618,348 from \$12,034,985 in the prior year. The \$1.6 million increase was primarily due to a \$1.5 million increase in CML expenditures, a decrease of \$0.6 million in PD expenses and a net increase of \$0.7 million in all other research and development activities.

Selling, General and Administrative

Selling, general and administrative expenses increased by \$514,882 or 8.3% to \$6,731,945 from \$6,217,063 in the prior year. The increase was primarily the result of an increase in investor relations costs of \$1.0 million and an increase in employee costs of \$0.3 million that were partly offset by a decrease in D&O insurance of \$0.6 million, a decrease in legal and consulting fees of \$0.4 million and a net increase of \$0.2 million in all other selling, general and administrative expenses.

Interest Income

Interest income increased by \$986,456 or 1,324.9% to \$1,060,909 from \$74,453 in the prior comparable period. The increase was driven by interest earned on U.S. Treasuries and money market instruments commencing in July 2022.

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 December 31, 2023, we generated aggregate cash proceeds of approximately \$23.9 million from private, state and federal contracts and grants. In December 2020, June 2021, and January 2023, the Company raised approximately \$14.6 million, \$41.1 million, and \$8.5 million respectively, in net proceeds from its 2020 IPO, its June 2021 Offering, and its January 2023 Offering, respectively.

On February 1, 2024, the Company entered into an At the Market Offering Agreement (the “At the Market Agreement”) with H.C. Wainwright & Co., LLC, as sales agent (the “Agent”), pursuant to which the Company may, from time to time, issue and sell shares of its Common Stock, in an aggregate offering price of up to \$5,659,255 through the Agent. Under the terms of the At the Market Agreement, the Agent may sell the shares of Common Stock at market prices by any method that is deemed to be an “at the market offering” as defined in Rule 415 under the Securities Act. 290,564 shares of Common Stock were sold pursuant to the At the Market Agreement and \$777,910 net proceeds were received from the Agent.

At December 31, 2023, the Company had working capital of \$10,772,447, an accumulated deficit of \$66,900,725, cash and cash equivalents of \$9,165,179, marketable securities of \$4,086,873 and accounts payable and accrued expenses of \$2,906,722.

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 initial public offering, we incurred additional costs associated with operating as a public company. We anticipate that we will need substantial additional funding in connection with our continuing operations.

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 \$66,900,725 at December 31, 2023. 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 \$10,772,447 at December 31, 2023. The Company intends to raise additional working capital in order to carry on its operations and current clinical trials. However, as certain elements of the Company's operating plan are outside of the Company's control, including the receipt of anticipated future grants and funding from future capital raises, they cannot be considered probable. If the Company does not receive additional working capital from future anticipated grants and future anticipated capital raises, its operating plan will be limited in scope to operating at its pre-IPO levels which were limited to basic research and development but excluded current and planned future clinical trials.

We have identified conditions and events that raise doubt about our ability to continue as a going concern and our independent registered public accounting firm has included an explanatory paragraph relating to our ability to continue as a going concern in its report on our audited financial statements for the years ended December 31, 2023 and 2022 included in this Report. These conditions raise substantial doubt regarding our ability to continue as a going concern for a period of one year after the date the financial statements included in this Report are issued. Our management's plans to alleviate the conditions that raise substantial doubt may include suspending or delaying certain research projects and capital expenditures and eliminating certain future operating expenses in order to fund operations at reduced levels for us to continue as a going concern for a period of 12 months from the date the financial statements are issued.

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 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 pandemics such as COVID-19;
- 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:

	Year Ended December 31,	
	2023	2022
Net cash used in operating activities	\$ (18,085,043)	\$ (17,351,103)
Net cash provided by (used in) investing activities	11,656,666	(16,005,708)
Net cash provided by (used in) financing activities	8,405,003	(204,769)
Net increase (decrease) in cash and cash equivalents	<u>\$ 1,976,626</u>	<u>\$ (33,561,580)</u>

Net Cash Flows Used in Operating Activities

Net cash flows used in operating activities for the year ended December 31, 2023 totaled \$18,085,043, and consisted primarily of a net loss of \$19,028,883 adjusted for non-cash stock compensation of \$500,148, depreciation and lease expense of \$172,746, decrease in accounts receivable of \$39,881, increase in prepaid expenses and other assets of \$55,387, decrease in accounts payable of \$504,406, decrease in prepaid research and development of \$897,803 and an decrease in accrued expenses and other current liabilities of \$138,481.

Net cash flows used in operating activities for the year ended December 31, 2022 totaled \$17,351,103, and consisted primarily of a net loss of \$18,054,155 adjusted for non-cash stock compensation of \$458,147, depreciation and lease expense of \$34,920, decrease in accounts receivable of \$70,258, decrease in prepaid expenses and other assets of \$1,339,273, decrease in accounts payable of \$61,395, increase in prepaid research and development of \$1,010,616 and an increase in accrued expenses and other current liabilities of \$317,325.

Cash Provided by (Used in) Investing Activities

Net cash flows provided by investing activities for the year ended December 31, 2023, totaled \$11,656,666, of which \$14,238 was used for the purchase of equipment, \$29,426,101 was used for the purchase of marketable securities investments and \$41,097,005 was provided by maturity of marketable securities.

Net cash flows used in investing activities for the year ended December 31, 2022, totaled \$16,005,708, of which \$243,255 was used for the purchase of equipment, \$20,725,462 was used for the purchase of marketable securities investments and \$4,963,009 was provided by maturity of marketable securities.

Cash Provided by (Used in) Financing Activities

Net cash provided by financing activities for the year ended December 31, 2023 totaled \$8,405,003, which consisted of \$8.54 million net from issuance of common stock and pre-funded warrants and \$138,556 of deferred offering costs.

Net cash used in financing activities for the year ended December 31, 2022 totaled \$204,769, which consisted of \$44,142 in proceeds from exercise of stock options and \$248,911 in debt payments.

We raised \$14.6 million, \$41.1 million and \$8.5 million in net proceeds from our 2020 IPO, June 2021 Offering and January 2023 Offering. We expect this trend of raising capital from a combination of grants and equity sales to continue for the foreseeable future.

Off-Balance Sheet Arrangements

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

Contractual Obligations and Commitments

On April 18, 2022, the Company entered into an operating lease agreement through September 30, 2025 for its office space in Lexington, Massachusetts to replace the office space in Boston, Massachusetts. The Company vacated the Boston office during the third quarter of 2022 without further contractual obligation. The Lexington lease contains escalating payments during the lease period. Upon execution of this lease agreement, the Company prepaid one month of rent, applied to the first month's rent, and a security deposit, which will be held in escrow and credited at the termination of the lease. Our total lease obligation is \$265,061, consisting of minimum annual rental obligations of \$150,095 for fiscal year 2024 and \$114,966 for fiscal year 2025.

Critical Accounting Policies and Significant Judgments and Estimates

This discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States, or 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 preclinical studies and consulting services. These costs are a significant component of our research and development expenses. Typically, upfront payments and milestone payments made for the licensing of technology are expensed as research and development in the period in which they are incurred, except for payments relating to intellectual property rights with future alternative use which will be expensed when the intellectual property is in use. Non-refundable advance payments for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses. The prepaid amounts are expensed as the related goods are delivered or the services are performed.

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.

Stock-Based Compensation

We have granted stock-based awards, consisting of non-qualified stock options, to our employees, certain non-employee consultants and members of our board of directors, both past and present. We measure stock-based compensation expense for stock options granted to our employees and directors on the date of grant and recognize the corresponding compensation expense of those awards over the requisite service period, which is generally the vesting period of the respective award.

We estimate the fair value of stock options granted to our employees and directors on the grant date, and the resulting stock-based compensation expense, using the Black-Scholes-Merton option pricing model.

The intrinsic value of all in the money outstanding options as of December 31, 2023 was approximately \$0.0 million, based on the closing price of our common stock of \$1.27 per share at December 31, 2023, all of which is related to vested options.

JOBS Act

The JOBS Act permits an emerging growth company such as us 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. We have elected to avail ourselves of the extended transition period for complying with new or revised financial accounting standards.

We will remain an emerging growth company until the earliest of (i) the last day of our first fiscal year in which we have total annual gross revenues of \$1.07 billion or more; (ii) the date on which we are deemed to be a “large accelerated filer” under the rules of the SEC with at least \$700.0 million of outstanding equity securities held by non-affiliates; (iii) the date on which we have issued more than \$1.0 billion in non-convertible debt securities during the previous three years; or (iv) the last day of our fiscal year following the fifth anniversary of the date of the completion of our December 2020 public offering.

Recent Accounting Pronouncements

The JOBS Act permits an emerging growth company such as us 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. We have 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, we 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 we either (i) irrevocably elect to “opt out” of such extended transition period or (ii) no longer qualify as an emerging growth company. Unless otherwise discussed below, the Company does not believe that the adoption of recently issued standards has had or may have a material impact on the Company's consolidated financial statements or disclosures

Item 7A. 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 8. Financial Statements and Supplementary Data.

The financial statements and the report of our independent registered public accounting firm (PCAOB ID:596) required to be filed pursuant to this Item 8 are appended to this Annual Report on Form 10-K. An index of those financial statements is found on page F-1 of this Annual Report on Form 10-K.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.**Evaluation of Disclosure Controls and Procedures**

As of the end of the period covered by this Report, management performed, with the participation of our principal executive and principal financial officers, an evaluation of the effectiveness of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act. 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 forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, to allow timely decisions regarding required disclosures. Based on the evaluation, our principal executive and principal financial officers concluded that, as of December 31, 2023, our disclosure controls and procedures were effective.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as such term is defined in Exchange Act Rule 13a-15(f). Management evaluated the effectiveness of our internal control over financial reporting using the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control Integrated Framework (the 2013 Framework). Based on this assessment, our management concluded that, as of December 31, 2023, our internal control over financial reporting was effective based on those criteria. All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. There were no changes in our internal control over financial reporting during the fiscal quarter ended December 31, 2023 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

This annual report does not include an attestation report of our registered public accounting firm due to the transition period established by the JOBS Act for emerging growth companies.

Item 9B. Other Information.

None.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Executive Officers and Directors

The following table sets forth the names, ages and positions of our executive officers and directors as of March 1, 2024:

Name	Age	Position
<i>Executive Officers:</i>		
Milton H. Werner, Ph.D.	61	President, Chief Executive Officer and Director
Joseph Frattaroli, C.P.A.	62	Chief Financial Officer ⁽⁷⁾
<i>Non-Employee Directors:</i>		
Gisele Dion ⁽¹⁾⁽²⁾⁽⁴⁾	57	Director
Roy Freeman, M.D. ⁽²⁾⁽³⁾	72	Director
Paul Grint, M.D. ⁽¹⁾⁽²⁾⁽³⁾⁽⁵⁾	66	Director
Dennis Berman ⁽¹⁾⁽³⁾⁽⁶⁾	73	Director

(1) Member of the audit committee

(2) Member of the compensation committee

(3) Member of the corporate governance and nominating committee

(4) Chair of audit committee

(5) Chair of compensation committee

(6) Chair of corporate governance and nominating committee

(7) As previously announced on January 16, 2024, on March 31, 2024, Mr. Frattaroli will step down from his role as Chief Financial Officer, and Garth Lees-Rolfe, our Vice President of Finance, is expected to take over this role.

Executive Officers

Milton H. Werner, Ph.D. has been our President and Chief Executive Officer and a member of our board of directors since our formation as a Delaware corporation in June 2010. He founded our predecessor, Inhibikase Therapeutics, LLC, in 2008 as an entrepreneurial start-up in Atlanta, Georgia with initial financial support from the Georgia Research Alliance. Prior to founding Inhibikase, from May 2007 until August 2008, Dr. Werner served as Director of Research at Celtaxsys, Inc., a cell-free immunotherapeutics company. From September 1996 until June 2007, Dr. Werner was a Head of the Laboratory of Molecular Biophysics at The Rockefeller University and departed the University at the rank of Associate Professor. While at The Rockefeller University, Dr. Werner focused on developing more complete understandings of mechanisms of human disease in immunology, oncology and infectious disease. Dr. Werner is the author or co-author of more than 70 research articles, reviews and book chapters and has given lectures on his research work on more than 150 occasions throughout the world. He is the recipient of numerous private and public research grants totaling more than \$21 million, and of several awards, including the Young Investigator Award from the Sidney Kimmel Cancer Foundation, the Research Chair from the Brain Tumor Society and a \$1 million Distinguished Young Scholars in Medical Research award from the W. M. Keck Foundation. He is also an Adjunct Full Professor in the School of Biology at the Georgia Institute of Technology and a Member of the Winship Cancer Institute of Emory University, both in Atlanta, Georgia. Dr. Werner received his Ph.D. in Chemistry from the University of California, Berkeley and his B.S. in Biochemistry from the University of Southern California. He also completed his post-doctoral training at the National Institute of Health with a specialization in structural biology. We believe Dr. Werner is qualified to serve on our board of directors because of the perspective and experience he provides as our founder and as our President and Chief Executive Officer, as well as his experience within the pharmaceutical industry, particularly in the area of neuroscience, infectious disease and drug discovery and development.

Joseph Frattaroli has served as our Chief Financial Officer since April 2018. From July 2015 through 2017, Mr. Frattaroli has served as an independent consultant to Danforth Advisors LLC, providing strategic advisory services to emerging public and private biotechnology and biopharmaceutical clients of Danforth Advisors LLC.

In January 2010, Mr. Frattaroli founded Flagship Consulting, Inc. through which he has provided chief financial officer and consulting services for the past 10 years to several emerging biopharmaceutical and medical device companies, with responsibilities that included capital formation, deal structuring, and assisting private companies in their transition to becoming publicly traded SEC registrants. Mr. Frattaroli is a certified public accountant with more than 15 years of experience in public company filings and compliance for Nasdaq and OTC Markets companies. Mr. Frattaroli received his B.S. in Accounting from Salem State University and was previously employed by Ernst & Young, LLP.

Key Non-Executive Officers

Surendra Singh, Ph.D. has served as our head of Chemistry, Manufacturing and Controls (CMC) as a consultant since August 2014. As our head of Chemistry, Manufacturing and Controls, Dr. Singh establishes and manages the commercial process, global outsourcing, and global vendor management, as well as participates in all aspects of the drafting and review of regulatory documents from the IND to NDA. Since 2011, Dr. Singh has served as chemical manufacturing and controls consultant at Syner-G Pharma Consulting, LLC, a pharmaceutical manufacturing consultancy. From 2001 to 2011, he served in various roles at Sunovion Pharmaceuticals Inc. and its predecessor, Sepracor Inc., including as a director of chemical process research. He is an expert in chemical process research and development, from lead optimization to launch, technology transfer and API manufacturing. Dr. Singh received his doctoral degree from the Indian Institute of Technology in 1991 and was a post-doctoral fellow at The Ohio State University from 1991 to 1994.

Terence Kelly, Ph.D. currently serves as our Medicinal Chemistry and Drug Discovery consultant. Since June 2014, he has served as a member of the board of directors of Cardax, Inc., a life sciences company that develops consumer health and pharmaceutical technologies. Dr. Kelly is a 30-year pharmaceutical industry veteran and, along with Dr. Werner, developed the RAMP™ approach to drug design. He is a founder of Kelly Pharma Research Consulting, LLC and has served as its President since January 2010. From June 2010 to July 2017, he held several positions at CoMentis, including President and CEO. From July 2002 to December 2009, he served as Vice-President of Medicinal Chemistry at Boehringer Ingelheim Pharmaceuticals, Inc. Dr. Kelly received his B.S. in Chemistry from Rensselaer Polytechnic Institute and his Ph.D. in Chemistry from the University of Texas at Austin. He also completed postdoctoral work in natural products synthesis at Yale University and received an M.B.A. from New York University, Stern School of Business.

Warren Olanow, M.D. is our lead medical consultant and Chief Executive Officer of CLINTREX. He is the former Henry P. and Georgette Goldschmidt Professor and Chairman of the Department of Neurology at the Mount Sinai School of Medicine in New York City, where he is presently Professor Emeritus in the Department of Neurology and in the Department of Neuroscience. Prior to joining Mount Sinai, he served on the faculties of McGill University, Duke University, and the University of South Florida. He is the former President of the Movement Disorder Society, past President of the International Society of Motor Disturbances, and former Treasurer of the American Neurological Association. He has served on the Board of Directors of the National Space Biomedical Research Institute and the executive committee of the Michael J. Fox Foundation Scientific Advisory Board, and he is the former Chairman of the Scientific Advisory Board of the Bachmann-Strauss Parkinson and of the Dystonia Foundation. Dr. Olanow is the former Co-Editor-in-Chief of the journal, *Movement Disorders*. He has been principal investigator of numerous studies leading to approval of drugs and devices for treating neurodegenerative diseases. Dr. Olanow received his medical degree from the University of Toronto, performed his neurology training at the New York Neurological Institute at Columbia Presbyterian Medical Center at Columbia University, and undertook postgraduate studies in neuroanatomy at Columbia University.

Non-Employee Directors

Dennis Berman has served as a member of our Board of Directors since December 22, 2020. Dennis Berman has been a co-founder, board member, and seed investor in many private biotechnology and technology companies, five of which have gone public. Currently, Mr. Berman is President of Molino Ventures, a Board advisory and venture capital firm focused on privately held and publicly held health care and technology companies in all stages of development. Previously, he was Co-founder and Executive Vice President of Corporate Development of Tocagen, a publicly traded gene therapy company utilizing a replicating retrovirus and prodrug to activate patients' immune systems against their cancers. Other public companies for which Mr. Berman has served as a seed investor, co-founder, and/or board member include Intervu (one of the first software-as-a-service companies), which was acquired by Akamai; Kintera (online fundraising pioneer), which was acquired by Blackbaud; Gensia (focused on purine/pyrimidine metabolism compounds), which was acquired by Teva; and Viagene (the first U.S. gene therapy company, which utilized a non-replicating retrovirus), which was acquired by Chiron/Novartis. In addition, he was co-founder of Genovo (a private gene therapy company founded by James Wilson at University of Pennsylvania). Mr. Berman also was a seed investor in Calabrian (a private water treatment company), which was acquired by SK Capital. Earlier, Mr. Berman was a corporate law partner at several large law firms, including Sonnenschein Nath & Rosenthal (now Dentons) and Reavis & McGrath (now Norton Rose Fulbright). Mr. Berman holds a Bachelor of Science from Wharton School in Accounting/ Economics, a Bachelor of Arts from the University of Pennsylvania in Economics and is a graduate of Harvard Law School. He has been an Entrepreneur in Residence at Harvard's Innovation Lab (i-lab) and a guest speaker at Harvard School of Public Health. We believe Mr. Berman's skills in corporate governance, corporate finance, and value creation in early and late stage pharmaceutical and biotechnology companies make him uniquely qualified to serve on our board of directors.

Gisele Dion has served as a member of the Board of Directors since September 1, 2022. Ms. Dion is the current Senior Vice President, Chief Accounting Officer and Corporate controller at Alnylam Pharmaceuticals, Inc. Ms. Dion is the former Chief Accounting Officer and Corporate Controller at Takeda Pharmaceutical Ltd. She also served as Senior Advisor to the Chief Financial Officer of Takeda Pharmaceutical Ltd. Prior to Takeda's acquisition of Shire Pharmaceuticals LLC, Ms. Dion was the Senior Vice President, Chief Accounting Officer and Corporate Controller at Shire Pharmaceuticals LLC, a biopharmaceutical company. Previous to Shire, Ms. Dion served as Corporate Controller and Senior Director of Technical Accounting at Biogen Inc., a biotechnology company. Ms. Dion currently serves on the board of Cytek Biosciences, Inc. where she is Chair of its Audit Committee. Her prior experience includes serving as a staff member of the Financial Accounting Standards Board (FASB) and she has served as an Audit Advisor Group Member for the Pharmaceutical Research and Manufacturers of America (PhRMA). Ms. Dion received a B.S. in Accounting and Management Information Systems from Fairfield University. We believe Ms. Dion's skills in corporate governance and corporate finance in early and late stage pharmaceutical and biotechnology companies make her uniquely qualified to serve on our board of directors.

Roy Freeman, M.D. has served as a member of our Board of Directors since December 22, 2020. Dr. Freeman is a Professor of Neurology at the Harvard Medical School and the Director of the Center for Autonomic and Peripheral Nerve Disorders at Beth Israel Deaconess Medical Center in Boston, Massachusetts. Dr. Freeman is the former chairman of the World Federation of Neurology research group on the autonomic nervous system, former president of the American Autonomic Society, and former chairman of the Autonomic Section of the American Academy of Neurology. He serves on the Executive Committee and the Steering Committee of the Analgesic, Anesthetic, and Addiction Clinical Trial Translations, Innovations, Opportunities, and Networks (ACTION), a public-private partnership with the United States FDA. Dr. Freeman is Editor-in-Chief of *Autonomic Neuroscience: Basic and Clinical* and on the editorial boards of *The Journal of the Peripheral Nervous System* and *Clinical Autonomic Research*. He is a founder of several companies in pain and neurodegenerative disease and is on the scientific advisory boards of many large and small pharmaceutical and biotechnology companies. He is a former director of Cutaneous Neurodiagnostic Life Sciences and NeuroBo Pharmaceuticals. His research and clinical interests are in biomarker development in neurodegenerative disease, the physiology and pathophysiology of the small nerve fibers and the autonomic nervous system, and clinical trial design methodology in peripheral and central nervous system disease. He is the principal investigator on NIH-funded studies on the neurological complications of diabetes, the neurobiology of stress, and biomarker development in neuropathic pain and alpha-synucleinopathies. He has been a principal investigator on many neurodegenerative diseases and neuropathic pain clinical trials. He has authored more than 300 original reports, chapters, and reviews. Dr. Freeman received his medical degree from the University of Cape Town. We believe Dr. Freeman's specific and extensive experience in clinical treatment of Parkinson's and other neurological disorders coupled with his extensive experience as a director of pharmaceutical companies and as an advisor of novel therapies for neurological diseases makes him uniquely qualified to serve on our board of directors.

Paul Grint, M.D. has served as a member of our Board of Directors since December 22, 2020. Dr. Paul Grint was most recently CEO and a member of the board of directors of AmpliPhi Biosciences, which merged with C3J Therapeutics to form Armata Pharmaceuticals. Dr. Grint has more than three decades of experience in biologics and small-molecule research and development, including the successful approval and commercialization of products in the infectious diseases, immunology, and oncology therapeutic areas. Dr. Grint has also served in senior management roles at Cerexa, Forest Laboratories, Kalypsys, Pfizer, IDEC Pharmaceuticals, and Schering-Plough Corporation. He is currently Executive Chairman at Codagenix, and a board member at Synedgen and Persephone Biosciences. He is a Fellow of the Royal College of Pathologists, a member of numerous professional and medical societies, and holds a bachelor's degree from St. Mary's Hospital College, University of London and a medical degree from St. Bartholomew's Hospital College, University of London. Dr. Grint's extensive leadership experience as both Chief Executive Officer and as a director of privately held and public companies along with his extensive experience in clinical pharmaceutical development makes him uniquely qualified to serve on our board of directors.

Scientific Advisory Board

We have assembled a highly qualified scientific advisory board that collectively have deep domain expertise in neurodegenerative diseases, infectious disease in the brain, drug development and translational medicine.

Dr. Ted Dawson, M.D., Ph.D., is a director at the Institute for Cell Engineering and Professor of Neurology at The John Hopkins University School of Medicine. He focuses on movement disorders, and many advances in neurobiology of disease have stemmed from Dr. Dawson's identification of the mechanisms of neuronal cell death and the elucidation of the molecular mechanisms of neurodegeneration. He pioneered the role of nitric oxide in neuronal injury in stroke and excitotoxicity and elucidated the molecular mechanisms by which nitric oxide and poly (ADP-ribose) polymerase kills neurons. His studies of nitric oxide led to major insights into the neurotransmitter functions of this gaseous messenger molecule. He co-discovered the neurotrophic properties of non-immunosuppressant immunophilin ligands. Dr. Dawson's discoveries have led to innovative approaches and helped with the enablement of the development of new agents to treat neurologic disorders, such as Parkinson's Disease and Alzheimer's disease as well as other neurodegenerative disorders. For his participation on the Scientific Advisory Board, Dr. Dawson has received options for 21,854 shares of our common stock with an exercise price of \$13.86 per share, which will expire on December 31, 2027.

Dr. Valina Dawson, Ph.D., is a Professor of Neurology, Neuroscience, Physiology and the Graduate Program in Cellular & Molecular Medicine at the John Hopkins University School of Medicine. She is co-director of the Neuroregeneration and Stem Cell Programs in the Institute for Cell Engineering. Dr. Dawson's laboratory is actively engaged in discovering and defining cell signaling pathways that lead to either neuronal survival or neuronal death. She explores the role of the monogenic forms of Parkinson's Disease with a focus on parkin, EIF4G1 and LRRK2 in order to begin to define the biochemical signaling important to Parkinson's Disease. She has developed yeast, cellular, fly and mouse models to explore the Parkinson's Disease causing mutations, and studied human neuronal cultures and human postmortem tissue to explore survival and disease signaling events relevant to Parkinson's Disease. and stroke as well as to define neuron survival networks. For her participation on the Scientific Advisory Board, Dr. Dawson has received options for 21,854 shares of our common stock with an exercise price of \$13.86 per share, which will expire on December 31, 2027.

Dr. Warren Olanow, M.D., FRCPC is a member of our Scientific Advisory Board. For a description of Dr. Olanow's business experience and qualifications please see above in this section titled "Directors, Executive Officers and Corporate Governance."

Dr. Robert Hauser is Professor of Neurology at the University of South Florida College of Medicine, in Tampa, Florida. He serves as Director of the USF Parkinson's Disease and Movement Disorders Center, a Parkinson Foundation Center of Excellence. Dr. Hauser earned a medical degree from Temple University School of Medicine in Philadelphia, Pennsylvania, and completed neurology training at the Eastern Virginia Graduate School of Medicine, in Norfolk, Virginia. Dr. Hauser completed a fellowship in Movement Disorders at the University of South Florida and became Center Director in 1994. Dr. Hauser has authored or co-authored more than 300 peer-reviewed publications and is one of the world's most cited Parkinson's Disease investigators. He is Past Chairman of the Interventional Neurology Section of the American Academy of Neurology, has served on the executive committee of the Parkinson's Study Group, and was a member of the steering committee for the NIH-sponsored Neuroprotective Exploratory Trials in Parkinson's Disease program (NET-PD). Dr. Hauser lectures frequently at scientific meetings and served as Chairman of the 2009 World Federation of Neurology International Congress on Parkinson's Disease and Related Disorders. He has extensive expertise in clinical trial design and execution. Outcome measures that he developed have become the gold standard for use in clinical trials. He maintains an active patient practice and has been voted a Top Doctor by his peers and Castle Connolly Medical Ltd. every year since 2003. His primary research interest is the development of new medical and surgical treatments for Parkinson's disease and other movement disorders.

Dr. Karl Kieburtz, M.D., M.P.H., is the Robert J. Joynt Professor in Neurology, Senior Associate Dean for Clinical Research and Director of the Clinical & Translational Science Institute at the University of Rochester Medical Center (URMC). He is also Professor of Public Health Sciences and of Environmental Medicine, and was the founding Director of the Center for Human Experimental Therapeutics (CHET). CHET conducts learning phase clinical trials in a wide spectrum of disorders in collaboration with investigators within the URMC as well as with colleagues throughout North America, Europe, Asia and Oceania. Dr. Kieburtz's primary clinical and research interests are neurodegenerative diseases affecting the basal ganglia, particularly Parkinson disease, Huntington disease, and HIV-related neurologic disorders. He is the principal investigator for the NINDS sponsored trials of neuroprotective agents for PD (NET-PD) and directed the Coordination Center for an NEI-funded consortium in neuro-ophthalmology. He completed his M.D. and M.P.H. degrees at the University of Rochester, as well as his neurology residency and a fellowship in experimental therapeutics.

Dr. Jeffrey H. Kordower, Ph.D., is the Alla V. and Solomon Jesmer Professor of Aging and Neurological Sciences, Rush University Medical Center. He is an international authority in the area of movement disorders, with special expertise in experimental therapeutics and pathogenesis in movement disorders. Dr. Kordower has been ranked 29th in Parkinson's disease expertise worldwide. He has performed numerous gene and cell therapy preclinical studies that have been translated into clinical trials. He has published landmark papers in the area of cell replacement strategies, including the first demonstration that fetal dopaminergic grafts can survive, innervate, and form synapses in patients with Parkinson's disease (*NEJM*). Furthermore, he demonstrated that long-term grafts in such patients can form Lewy bodies (*Nature Medicine*). He has co-authored a paper in *Nature* demonstrating that human dopaminergic stem cells can survive and function in parkinsonian mice, rats, and monkeys. With regard to gene therapy, he published the lead article in *Science* demonstrating that gene delivery GDNF can prevent the emergence of motor symptoms and prevents nigrostriatal degeneration in nonhuman primate models of Parkinson's disease. Dr. Kordower was also the first to demonstrate that gene delivery of CNTF can obviate neurodegenerative processes in a nonhuman primate model of Huntington's disease. Dr. Kordower has published more than 350 manuscripts and chapters, 14 of which are citation classics. He has lectured all over the world and has served on more than 20 journal editorial boards (Sections Head and Associate Editor on two, including Movement Disorders). He has also served on the program committee for the World Parkinson's Congress, is a Past-President of ASNTR, and is both a founding SAB member and two-time Executive Committee member of The Michael J. Fox Foundation. Dr. Kordower received B.A., M.A., and Ph.D. degrees from the City University of New York (CUNY). He was awarded an Honorary Doctor of Science degree from CUNY in 2004.

Dr. Kenneth Marek is President and senior scientist at the Institute for Neurodegenerative Disorders. Dr. Marek's major research interests include identification of biomarkers for early detection, assessment of disease progression, and development of new treatments for Parkinson's Disease and Alzheimer's disease and related neurodegenerative disorders. His specific interest has been in *in vivo* neuroreceptor imaging biomarkers. He has authored numerous neurology and neuroscience publications on these topics. Dr. Marek is the principal investigator of several ongoing multi-center international studies, including the Parkinson's Progression Marker Initiative (PPMI), the Parkinson Associated Risk Syndrome (PARS) study, and Pathways to Prevention (P2P). Dr. Marek serves on the scientific advisory board of The Michael J. Fox Foundation and is a special advisor to the foundation. He also was a co-founder of Molecular NeuroImaging, LLC, a company providing discovery and clinical neuroimaging research services. He received an A.B. in Biochemistry from Princeton University and an M.D. from Yale University.

Dr. Jay Pasricha is Vice-Chair of the Department of Medicine and Professor of Medicine and Neuroscience at The Johns Hopkins University School of Medicine, and Professor of Innovation Management at Johns Hopkins Carey Business School. He is Director of the Johns Hopkins Center for Neurogastroenterology and Director of the Amos Food, Body, and Mind Center at Johns Hopkins. Prior to his positions at Johns Hopkins, Dr. Pasricha served as Chief of Gastroenterology at Stanford University School of Medicine from 2007–2012. Prior to that, he led the GI Division at the University of Texas Medical Branch, where he was the Bassel and Frances Blanton Distinguished Professor in Internal Medicine. His specific interests are focused on molecular mechanisms of visceral pain, gastrointestinal motility, the gut-brain axis, microbiota, neuromodulation, and neural control of glycemic control and obesity. His clinical interests include GI motility disorders and abdominal pain as well as the development of novel endoscopic procedures and devices for a variety of gastrointestinal disorders. He has consistently been on Castle Connolly list of America's "Top Docs" as well as "Best Doctors" and has authored more than 300 manuscripts/book chapters. He has served on the National Commission on Digestive Diseases, appointed by Congress to provide a "roadmap" for progress in gastrointestinal disorders. He is also the founding Chair of the Center for Gastrointestinal Innovation and Technology, created by the AGA (American Gastroenterological Association). Dr. Pasricha served on the FDA GI Drug Advisory Committee for several years and continues to provide advice to the agency on an ad hoc basis. Dr. Pasricha holds more than 50 patents issued by the USPTO and has co-founded several companies within the Medtech and biotech GI space including Apollo Endosurgery, Enterastim, First Aid Shot Therapeutics (FAST), Neurogastrx, Orphomed, and Glyscend. Dr. Pasricha received his Doctor of Medicine from the All-India Institute of Medical Sciences and training in New Delhi. Subsequently, he trained in internal medicine and pulmonology at Georgetown University-DC General Hospital and Tufts-New England Medical Center, respectively. Thereafter, he trained in gastroenterology at Johns Hopkins Hospital.

Family Relationships

No family relationships exist between any director, executive officer or person nominated or chosen to be a director or officer.

Board of Directors Composition

Our board of directors currently consists of five members. The number of directors will be fixed by our board of directors, subject to the terms of our amended and restated certificate of incorporation and amended and restated bylaws. Each of our current directors will continue to serve as a director until the election and qualification of his or her successor, or until his or her earlier death, resignation or removal.

Our amended and restated certificate of incorporation provides that our board of directors will be divided into three classes with staggered three-year terms. Only one class of directors will be elected at each annual meeting of stockholders, with the other classes continuing for the remainder of their respective three-year terms. Our current directors are divided among the three classes as follows:

- the Class I director is Dr. Werner, and his term will expire at the annual meeting of stockholders to be held in 2024;
- the Class II directors are Dr. Freeman and Dr. Grint, and their terms will expire at the annual meeting of stockholders to be held in 2025; and
- the Class III directors are Mr. Berman and Ms. Dion, and their terms will expire at the annual meeting of stockholders to be held in 2026.

At each annual meeting of stockholders, upon the expiration of the term of a class of directors, the successor to each such director in the class will be elected to serve from the time of election and qualification until the third annual meeting following his or her election and until his or her successor is duly elected and qualified, in accordance with our amended and restated certificate of incorporation. Any additional directorships resulting from an increase in the number of directors will be distributed among the three classes so that, as nearly as possible, each class will consist of one-third of our directors.

This classification of our board of directors may have the effect of delaying or preventing changes in control of our company.

In addition, under the terms of our amended and restated certificate of incorporation and our amended and restated bylaws, members of our board of directors may only be removed for cause. This may also have the effect of delaying or preventing changes in control of our company.

Director Independence

Our common stock is listed on the Nasdaq Capital Market, or Nasdaq. Under the rules of Nasdaq, independent directors must comprise a majority of a listed company's board of directors within one year of the completion of its initial public offering. In addition, the rules of Nasdaq require that, subject to specified exceptions, each member of a listed company's audit, compensation and corporate governance and nominating committees be independent. Audit committee members and compensation committee members must also satisfy the independence criteria set forth in Rule 10A-3 and Rule 10C-1, respectively, under the Exchange Act. Under the rules of Nasdaq, a director will only qualify as an "independent director" if, in the opinion of that company's board of directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director.

To be considered to be independent for purposes of Rule 10A-3 and under the rules of Nasdaq, a member of an audit committee of a listed company may not, other than in his or her capacity as a member of the audit committee, the board of directors, or any other board of directors committee: (1) accept, directly or indirectly, any consulting, advisory, or other compensatory fee from the listed company or any of its subsidiaries; or (2) be an affiliated person of the listed company or any of its subsidiaries.

To be considered independent for purposes of Rule 10C-1 and under the rules of Nasdaq, the board of directors must affirmatively determine that each member of the compensation committee is independent, including a consideration of all factors specifically relevant to determining whether the director has a relationship to the company which is material to that director's ability to be independent from management in connection with the duties of a compensation committee member, including, but not limited to: (i) the source of compensation of such director, including any consulting, advisory or other compensatory fee paid by the company to such director; and (ii) whether such director is affiliated with the company, a subsidiary of the company or an affiliate of a subsidiary of the company.

Our board of directors undertook a review of its composition, the composition of its committees and the independence of our directors and considered whether any director has a material relationship with us that could compromise his or her ability to exercise independent judgment in carrying out his or her responsibilities. Based upon information requested from and provided by each non-employee director concerning his or her background, employment and affiliations, including family relationships, our board of directors has determined that none of our non-employee directors have relationships that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director and that each of these directors is “independent” as that term is defined under the rules of Nasdaq and Rule 10A-3 and Rule 10C-1 under the Exchange Act. Only Dr. Werner is not independent under Nasdaq’s independence standards.

In making these determinations, our board of directors considered the current and prior relationships that each non-employee director has with our company and all other facts and circumstances our board of directors deemed relevant in determining their independence, including the beneficial ownership of our capital stock by each non-employee director, and the transactions involving them described in the section titled “Certain Relationships and Related Party Transactions.”

Board of Directors Leadership Structure

As a general policy, our board of directors believes that separation of the positions of Chairperson and Chief Executive Officer reinforces the independence of our board of directors from management, creates an environment that encourages objective oversight of management’s performance and enhances the effectiveness of our board of directors as a whole. As such, Dr. Werner serves as our President and Chief Executive Officer. At the present time the Company does not expect to have a Chairperson of our board of directors. Such Chairperson of our board of directors, when appointed, will not be an officer. We expect and intend the positions of Chairperson of our board of directors, when and if appointed, and Chief Executive Officer to continue to be held by two separate individuals in the future.

Board of Directors Committees

The Board of Directors has established three standing committees of the board consisting of an audit committee, a compensation committee and a corporate governance and nominating committee, each of which will have the composition and the responsibilities described below.

Audit Committee

Ms. Dion, Dr. Grint and Mr. Berman each of whom is a non-employee member of our Board of Directors, comprise our audit committee. Ms. Dion is the chair of our audit committee, and is our audit committee financial expert, as that term is defined under the applicable SEC rules, and possesses financial sophistication, as defined under the rules of Nasdaq. All of the members of our audit committee are independent, as that term is defined under the rules of Nasdaq. Our audit committee is responsible for overseeing our corporate accounting and financial reporting process, assisting our board of directors in monitoring our financial systems, and overseeing legal, healthcare and regulatory compliance. Our audit committee will also:

- select and hire the independent registered public accounting firm to audit our financial statements;
- help to ensure the independence and performance of the independent registered public accounting firm;
- approve audit and non-audit services and fees;
- review financial statements and discuss with management and the independent registered public accounting firm our annual audited and quarterly financial statements, the results of the independent audit and the quarterly reviews and the reports and certifications regarding internal controls over financial reporting and disclosure controls;
- prepare the audit committee report that the SEC requires to be included in our annual proxy statement;
- review reports and communications from the independent registered public accounting firm;
- review the adequacy and effectiveness of our internal controls and disclosure controls and procedure;
- review our policies on risk assessment and risk management;
- review related party transactions; and
- establish and oversee procedures for the receipt, retention and treatment of accounting related complaints and the confidential submission by our employees of concerns regarding questionable accounting or auditing matters.

Our audit committee operates under a written charter, which we believe satisfies the applicable rules of the SEC and the listing standards of Nasdaq.

Compensation Committee

Dr. Grint, Ms. Dion and Dr. Freeman each of whom is a non-employee member of our Board of Directors, comprise our compensation committee. Dr. Grint is the chair of our compensation committee. All of the members of our compensation committee are independent, as that term is defined under the rules of Nasdaq. Our compensation committee oversees our compensation policies, plans and benefits programs. The compensation committee will also:

- oversee our overall compensation philosophy and compensation policies, plans and benefit programs;
- review and recommend to our board of directors for approval compensation for our executive officers and directors;
- prepare the compensation committee report that the SEC would require to be included in our annual proxy statement if we were no longer deemed to be an emerging growth company or a smaller reporting company; and
- administer our equity compensation plans.

Our compensation committee operates under a written charter, which satisfies the applicable rules of the SEC and the listing standards of Nasdaq.

Corporate Governance and Nominating Committee

Mr. Berman, Dr. Grint and Dr. Freeman each of whom is a non-employee member of our Board of Directors, comprise our corporate governance and nominating committee. Mr. Berman is the chair of our corporate governance and nominating committee. All members are independent, as that term is defined under the rules of Nasdaq. Our corporate governance and nominating committee oversees and assists our board of directors in reviewing and recommending nominees for election as directors. Specifically, the corporate governance and nominating committee will:

- identify, evaluate and make recommendations to our board of directors regarding nominees for election to our board of directors and its committees;
- consider and make recommendations to our board of directors regarding the composition of our board of directors and its committees;
- review developments in corporate governance practices;
- evaluate the adequacy of our corporate governance practices and reporting; and
- evaluate the performance of our board of directors and of individual directors.

Our corporate governance and nominating committee operates under a written charter, which we believe satisfies the applicable rules of the SEC and the listing standards of Nasdaq.

Compensation Committee Interlocks and Inside Participation

None of the members of our compensation committee are or have been an officer or employee of our company. None of our executive officers currently serve, or in the past fiscal year has served, on the board of directors or compensation committee (or other board of directors' committee performing equivalent functions) of any entity that has one or more executive officers serving on our board of directors or compensation committee.

Risk Oversight

In its governance role, and particularly in exercising its duty of care and diligence, the board of directors is responsible for ensuring that appropriate risk management policies and procedures are in place to protect the Company's assets and business. Our board of directors has broad and ultimate oversight responsibility for our risk management processes and programs and executive management is responsible for the day-to-day evaluation and management of risks to the Company.

Code of Business Conduct and Ethics

We have adopted a written code of business conduct and ethics that applies to our directors, officers and employees, including our principal executive officer, principal financial officer and principal accounting officer or controller, or persons performing similar functions. The code of business conduct and ethics is available on our website at www.inhibikase.com. We intend to disclose future amendments to such code, or any waivers of its requirements, applicable to any principal executive officer, principal financial officer and principal accounting officer or controller or persons performing similar functions or our directors on our website identified above. The inclusion of our website address in this Report does not include or incorporate by reference the information on our website into this Report. We will provide any person, without charge, upon request, a copy of our code of conduct and ethics. Such requests should be made in writing to the attention of Dr. Milton Werner, President and CEO at Inhibikase Therapeutics, Inc., 3350 Riverwood Parkway SE, Suite, 1900, Atlanta, GA 30339.

Limitation of Liability and Indemnification

Our amended and restated certificate of incorporation and amended and restated bylaws, which became effective upon the completion of the December 2020 initial public offering, provides that we indemnify our directors and officers, and may indemnify our employees and other agents, to the fullest extent permitted by Delaware law. Delaware law prohibits our amended and restated certificate of incorporation from limiting the liability of our directors for the following:

- any breach of the director's duty of loyalty to us or to our stockholders;
- acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law;
- unlawful payment of dividends or unlawful stock repurchases or redemptions; and
- any transaction from which the director derived an improper personal benefit.

If Delaware law is amended to authorize corporate action further eliminating or limiting the personal liability of a director, then the liability of our directors will be eliminated or limited to the fullest extent permitted by Delaware law, as so amended. Our amended and restated certificate of incorporation does not eliminate a director's duty of care and, in appropriate circumstances, equitable remedies, such as injunctive or other forms of non-monetary relief, remain available under Delaware law. This provision also does not affect a director's responsibilities under any other laws, such as the federal securities laws or other state or federal laws. Under our amended and restated bylaws, we will also be empowered to purchase insurance on behalf of any person whom we are required or permitted to indemnify.

In the case of an action or proceeding by or in the right of our company or any of our subsidiaries, no indemnification will be provided for any claim where a court determines that the indemnified party is prohibited from receiving indemnification. We believe that these charter and bylaw provisions are necessary to attract and retain qualified persons as directors and officers.

The limitation of liability and indemnification provisions in our amended and restated certificate of incorporation and amended and restated bylaws may discourage stockholders from bringing a lawsuit against directors for breach of their fiduciary duties. They may also reduce the likelihood of derivative litigation against directors and officers, even though an action, if successful, might benefit us and our stockholders. Moreover, a stockholder's investment may be harmed to the extent we pay the costs of settlement and damage awards against directors and officers pursuant to these indemnification provisions.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to our directors, officers and controlling persons pursuant to the foregoing provisions, or otherwise, we have been advised that, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act, and is, therefore, unenforceable. There is no pending litigation or proceeding naming any of our directors or officers as to which indemnification is being sought, nor are we aware of any pending or threatened litigation that may result in claims for indemnification by any director or officer.

Delinquent Section 16(a) Reports

Section 16(a) of the Exchange Act requires our executive officers and directors, and persons who beneficially own more than 10% of a registered class of our common stock, to file initial reports of ownership and reports of changes in ownership with the SEC. These officers, directors and stockholders are required by SEC regulations to furnish us with copies of all reports that they file.

Based solely upon a review of copies of the reports furnished to us during the year ended December 31, 2023 and thereafter, or any written representations received by us from directors, officers and beneficial owners of more than 10% of our common stock ("reporting persons") that no other reports were required. We believe that all reporting persons filed on a timely basis all reports required by Section 16(a) of the Exchange Act during the year ended December 31, 2023.

Item 11. Executive Compensation.

Our named executive officers for the fiscal year ended December 31, 2023 (also referred to herein as “fiscal 2023”), who consist of our principal executive officer and our next most highly compensated executive officer, are:

- Milton H. Werner, Ph.D., our President and Chief Executive Officer; and
- Joseph Frattaroli, C.P.A., our Chief Financial Officer¹

(1) As previously announced on January 16, 2024, on March 31, 2024, Mr. Frattaroli will step down from his role as Chief Financial Officer, and Garth Lees-Rolfe, our Vice President of Finance, is expected to take over this role.

Summary Compensation Table

The following table sets forth information regarding the compensation of our named executive officers for the fiscal years ended December 31, 2023 and December 31, 2022:

Name and Principal Position	Year	Salary \$(1)	Bonus (\$)	Option Awards \$(2)	Non-Equity Incentive Plan Compensation \$(3)	All Other Compensation \$(4)	Total (\$)
Milton H. Werner, Ph.D. <i>President and Chief Executive Officer</i>	2023	510,000	—	113,472	170,850	17,107	811,429
	2022	500,833	—	85,865	140,250	17,107	744,055
Joseph Frattaroli, C.P.A. <i>Chief Financial Officer</i>	2023	408,333	—	48,631	123,000	—	579,964
	2022	395,833	—	42,932	136,000	—	574,765

- (1) Dr. Werner’s annual base salary rate was \$510,000 for the duration of fiscal 2023. Mr. Frattaroli’s annual base salary rate increased from \$400,000 to \$410,000 effective March 1, 2023.
- (2) The amount reported in this column for each named executive officer represents the aggregate grant date fair value of the option award made to such named executive officer, as calculated in accordance with FASB Accounting Standards Codification Topic 718, or ASC 718. The calculation of the grant date fair value of the option awards disclosed in this column is based on a risk-free interest rate of 4.3%, an expected volatility rate of 98.13%, an expected term of 4.5 years and an expected dividend yield of 0%. The calculation of the option awards disclosed in this column is based on a risk-free interest rate of 1.7%, expected volatility of 84.15%, expected term of 4.5 years and an expected dividend yield of 0% for the year 2022.
- (3) The amount reported in this column for each named executive officer represents the award earned by such named executive officer under our annual performance-based cash incentive program in respect of fiscal 2023 performance. These amounts were paid in 2024.
- (4) The amount reported in this column represents \$5,023 paid by us for Dr. Werner’s life insurance policy premiums and \$12,084 paid by us for Dr. Werner’s automobile expenses.

Outstanding Equity Awards at Fiscal Year-End

The following table sets forth information concerning outstanding equity awards held by each of our named executive officers as of December 31, 2023:

Name	Grant Date	Option Awards				
		Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Equity incentive awards: number of securities underlying unexercised unearned options (#)	Option Exercise Price (\$)	Option Expiration Date
Milton H. Werner	11/1/2015 (1)	3,643	—	—	13.86	11/1/2025
	11/1/2016 (2)	3,643	—	—	13.86	11/1/2026
	11/1/2017 (3)	3,643	—	—	13.86	11/1/2027
	11/1/2018 (4)	3,643	—	—	28.76	11/1/2028
	11/1/2019 (5)	3,643	—	—	33.43	11/1/2029
	12/22/2020 (7)	16,667	—	—	60.00	12/22/2027
	3/7/2022 (8)	12,153	8,681	—	6.42	3/7/2029
	3/7/2022 (9)	—	—	41,667	6.42	3/7/2029
	3/1/2023 (10)	—	35,000	—	4.44	3/1/2030
	3/1/2023 (11)	—	—	17,500	4.44	3/1/2030
	Joseph Frattaroli	8/25/2020 (6)	3,643	—	—	35.42
8/25/2020 (6)		25,000	—	—	35.42	8/25/2027
12/22/2020 (7)		16,667	—	—	60.00	12/22/2027
3/7/2022 (8)		6,077	4,304	—	6.42	3/7/2029
3/7/2022 (9)		—	—	20,834	6.42	3/7/2029
3/1/2023 (10)		—	15,000	—	4.44	3/1/2030
3/1/2023 (11)		—	—	7,500	4.44	3/1/2030

- (1) All of the shares subject to this option vested as of November 1, 2016.
- (2) All of the shares subject to this option vested as of November 1, 2017.
- (3) All of the shares subject to this option vested as of November 1, 2018.
- (4) All of the shares subject to this option vested as of November 1, 2019.
- (5) All of the shares subject to this option vested as of November 1, 2020.
- (6) The option grant on August 25, 2020 was issued to Flagship Consulting, Inc. (“Flagship”). Flagship is owned and controlled by Mr. Frattaroli. All of the shares subject to this option vested as of August 25, 2020.
- (7) With respect to the option awards granted to each of Dr. Werner and Mr. Frattaroli on December 22, 2020, one-third of each such option award vested and became exercisable on the first anniversary of the closing of our initial public offering (i.e., December 28, 2021), and the remainder vested and became exercisable in 24 equal monthly installments thereafter (commencing with January 1, 2022), subject generally to the relevant named executive officer’s continued service through each vesting date.
- (8) With respect to the option awards granted to each of Dr. Werner and Mr. Frattaroli on March 7, 2022 that are disclosed in these rows, one-third of each such option award vested and became exercisable on March 7, 2023, and the remaining portion will vest and become exercisable in 24 equal monthly installments thereafter (commencing with April 1, 2023), subject generally to the relevant named executive officer’s continued service through each vesting date.
- (9) With respect to the option awards granted to each of Dr. Werner and Mr. Frattaroli on March 7, 2022 that are disclosed in these rows, each such option award is subject to performance conditions and will vest and become exercisable only if and when the performance conditions have been met. There is no assurance that the performance conditions will be met, and therefore, all or a portion of these option awards may never vest or become exercisable. As of December 31, 2023, no performance conditions were met.
- (10) With respect to the option awards granted to each of Dr. Werner and Mr. Frattaroli on March 1, 2023 that are disclosed in these rows, one-third of each such option award will vest and become exercisable on March 1, 2024, and the remaining portion will vest and become exercisable in 24 equal monthly installments thereafter (commencing with April 1, 2024), subject generally to the relevant named executive officer’s continued service through each vesting date.
- (11) With respect to the option awards granted to each of Dr. Werner and Mr. Frattaroli on March 1, 2023 that are disclosed in these rows, each such option award is subject to performance conditions and will vest and become exercisable only if and when the performance conditions have been met. There is

no assurance that the performance conditions will be met, and therefore, all or a portion of these option awards may never vest or become exercisable. As of December 31, 2023, no performance conditions were met.

Narrative Disclosure to Summary Compensation Table

Milton H. Werner, Ph.D. Employment Agreement (the "Werner Employment Agreement")

Dr. Werner currently receives an annual base salary of \$510,000 and is eligible to receive an annual performance-based cash incentive with a target amount equal to 50% of his annual base salary, which incentive is earned based on the achievement of performance goals established by the compensation committee of the board of directors in the first quarter of the relevant fiscal year. The performance goals may include a number of factors, such as the successful progression of clinical trials, pre-clinical trials and development, the successful submission of regulatory filings, the discovery and development of additional candidate molecules, the entry into of one or more strategic partnerships, the adequacy of the Company's working capital, investor relations and successful organizational growth.

Pursuant to the Werner Employment Agreement, Dr. Werner is subject to one-year post-termination non-competition and non-solicitation of employees and clients covenants. He is also bound by confidentiality obligations.

In the event of a termination of Dr. Werner's employment by the Company without "Cause" or by Dr. Werner for "Good Reason" that, in each case, occurs other than within 12 months following the consummation of a "Change in Control" (as such terms are defined in the Werner Employment Agreement and summarized below), Dr. Werner is entitled to receive: (i) an amount equal to 12 months of his base salary, paid out in equal installments over a six-month period in accordance with the Company's normal payroll practices; (ii) payment of any annual bonus accrued for the year prior to the year of termination (to the extent not already paid); (iii) payment of a pro-rated annual bonus for the year of termination, with the amount based on actual performance through the end of the year of termination and the pro-ration based on the number of days that Dr. Werner was employed during the year of termination, paid when annual bonuses are paid to other senior executives of the Company; (iv) reimbursement of Dr. Werner's COBRA premiums for up to 12 months post-termination; and (v) full vesting of any outstanding, unvested equity awards granted to him by the Company. Dr. Werner's outstanding vested stock options will generally remain exercisable no longer than six 6 months following such a termination (and in no event past the expiration date).

In the event of a termination of Dr. Werner's employment by the Company without "Cause" or by Dr. Werner for "Good Reason" that, in each case, occurs within 12 months following the consummation of a "Change in Control," Dr. Werner is entitled to receive: (i) an amount equal to 18 months of his base salary, paid out in equal installments over a 12-month period in accordance with the Company's normal payroll practices; (ii) payment of any annual bonus accrued for the year prior to the year of termination (to the extent not already paid); (iii) an amount equal to 100% of his-then target annual bonus, paid when annual bonuses are paid to other senior executives of the Company; (iv) payment of a pro-rated target annual bonus for the year of termination, with the pro-ration based on the number of days that Dr. Werner was employed during the year of termination, paid when annual bonuses are paid to other senior executives of the Company; (v) reimbursement of Dr. Werner's COBRA premiums for up to 18 months post-termination; and (vi) full vesting of any outstanding, unvested equity awards granted to him by the Company. Dr. Werner's outstanding vested stock options will generally remain exercisable no longer than six months following such a termination (and in no event past the expiration date).

The receipt of any termination benefits described above is subject to Dr. Werner's execution of a release of claims in favor of the Company, a form of which is attached as an exhibit to the Werner Employment Agreement.

In the event of Dr. Werner's termination due to death or disability, Dr. Werner will be entitled to full vesting of any outstanding, unvested equity awards granted to him by the Company.

To comply with Massachusetts law governing non-competition agreements, the Werner Employment Agreement also provides for monthly severance payments in connection with any termination other than a termination by the Company without "Cause", by Dr. Werner for "Good Reason" or due to his death. Such severance payments are in an aggregate amount equal to one-half of Dr. Werner's highest annual base salary during the two years preceding termination. Such severance payments will be paid over either (i) a six-month period in the event of a termination that is not in connection with a Change in Control, or (ii) a 12-month period in the event the termination occurs within 12 months following a Change in Control.

Under the Werner Employment Agreement, "Cause" means generally any of Dr. Werner's: (i) conviction of or plea of nolo contendere to a felony; (ii) commission of fraud, misappropriation or embezzlement against any person; (iii) theft or misappropriation of Company property; (iv) breach of the Werner Employment Agreement (subject to a cure right); (v) willful or gross neglect of his

duties (subject to a cure right); (vi) willful or gross misconduct his performance of his duties (subject to a cure right); or (vii) willful violation of any material Company policy (subject to a cure right).

“Good Reason” means generally any of the following actions initiated by the Company: (i) a material diminution in Dr. Werner’s authority, duties or responsibilities; (ii) a material diminution in Dr. Werner’s base salary that persists for longer than 12 months; or (iii) a material breach of the Werner Employment Agreement. For “Good Reason” to exist, Dr. Werner must provide notice to the Company within 90 days of the initial existence of one of the above conditions; the Company must fail to cure such condition within 30 days; and Dr. Werner must terminate his employment within 180 days following the initial existence of the condition.

“Change in Control” means generally any of: (i) a merger or consolidation of the Company with another corporation (other than a transaction in which the voting securities outstanding prior to the transaction continue to represent more than 50% of the total voting power of the surviving entity after the transaction); (ii) the approval of a plan of complete liquidation of the Company or an agreement for the sale of all or substantially all of the Company’s assets; or (iii) a person or entity becomes the beneficial owner of securities of the Company representing 50% or more of the total voting power of the Company.

Joseph Frattaroli, C.P.A. Employment Agreement (the “Frattaroli Employment Agreement”)

Mr. Frattaroli receives an annual base salary of \$410,000 (with the increase from \$400,000 to such rate effective March 1, 2023) and is eligible to receive an annual performance-based cash incentive with a target amount equal to 40% of his annual base salary, which incentive is earned based on the achievement of performance goals established by the compensation committee of the board of directors in the first quarter of the year. The performance goals may include a number of factors, such as the successful progression of clinical trials, pre-clinical trials, and development, the successful submission of regulatory filings, the adequacy of the Company’s working capital, investor relations, financial reporting and operations, analyst coverage, tax strategy, strategy for maintaining Nasdaq listing, budgeting and successful organizational growth.

Pursuant to the Frattaroli Employment Agreement, Mr. Frattaroli is subject to one-year post-termination non-competition and non-solicitation of employees and clients covenants. He is also bound by confidentiality obligations.

In the event of a termination of Mr. Frattaroli’s employment by the Company without “Cause” or by Mr. Frattaroli for “Good Reason” that, in each case, occurs other than within 12 months following the consummation of a “Change in Control” (as such terms are defined in the Frattaroli Employment Agreement and summarized below), Mr. Frattaroli is entitled to receive: (i) an amount equal to nine months of his base salary, paid out in equal installments over a nine-month period in accordance with the Company’s normal payroll practices; (ii) payment of any annual bonus accrued for the year prior to the year of termination (to the extent not already paid); (iii) payment of a pro-rated annual bonus for the year of termination, with the amount based on actual performance through the end of the year of termination and the pro-ration based on the number of days that Mr. Frattaroli was employed during the year of termination, paid when annual bonuses are paid to other senior executives of the Company; and (iv) reimbursement for the difference between the cost of COBRA and Mr. Frattaroli’s contribution for health insurance for up to nine months following termination.

In the event of a termination of Mr. Frattaroli’s employment by the Company without “Cause” or by Mr. Frattaroli for “Good Reason” that, in each case, occurs within 12 months following the consummation of a “Change in Control,” Mr. Frattaroli is entitled to receive: (i) an amount equal to 12 months of his base salary, paid in a lump sum; (ii) payment of any annual bonus accrued for the year prior to the year of termination (to the extent not already paid); (iii) an amount equal to 100% of his-then target annual bonus, paid when annual bonuses are paid to other senior executives of the Company; (iv) payment of a pro-rated target annual bonus for the year of termination, with the pro-ration based on the number of days that Mr. Frattaroli was employed during the year of termination, paid when annual bonuses are paid to other senior executives of the Company; (v) reimbursement for the difference between the cost of COBRA and Mr. Frattaroli’s contribution for health insurance for up to 12 months following termination; and (vi) full vesting for any outstanding, unvested equity awards granted to him by the Company.

The receipt of any termination benefits described above is subject to Mr. Frattaroli’s execution of a release of claims in favor of the Company, a form of which is attached as an exhibit to the Frattaroli Employment Agreement.

To comply with Massachusetts law governing non-competition agreements, the Frattaroli Employment Agreement also provides for monthly severance payments in connection with any termination other than a termination by the Company without “Cause”, by Mr. Frattaroli for “Good Reason” or due to his death. Such severance payments are in an aggregate amount equal to one-half of Mr. Frattaroli’s highest annual base salary during the two years preceding termination. Such severance payments will be paid over either (i) a nine-month period in the event of a termination that is not in connection with a Change in Control, or (ii) a 12-month period in the event the termination occurs within 12 months following a Change in Control.

Under the Frattaroli Employment Agreement, “Cause” means generally any of Mr. Frattaroli’s: (i) commission of an act of disloyalty, dishonesty, breach of trust, fraud, misconduct, bad faith, embezzlement, misappropriation of Company assets, or destruction of Company property; (ii) gross negligence in the performance of employment duties; (iii) refusal, failure or willful nonfeasance to perform employment duties; (iv) failure to comply with Company policy (subject to a cure right); (v) conduct which is materially detrimental to the reputation, goodwill or business operation of the Company; (vi) conviction of, or plea of nolo contendere to, a felony; or (vii) a breach of the Frattaroli Employment Agreement by Mr. Frattaroli (subject to a cure right).

“Good Reason” and “Change in Control” under the Frattaroli Employment Agreement have the same meaning as those provided in the Werner Employment Agreement, as described above.

As previously disclosed in the Form 8-K dated January 16, 2024, in connection with Mr. Frattaroli’s planned retirement on March 31, 2024, the compensation committee of our board of directors has authorized the extension of the exercise period for each of Mr. Frattaroli’s vested option awards subject to time-based vesting until the original expiration date of each of such option award. Mr. Frattaroli will not be entitled to any severance in connection with such resignation.

Equity Compensation

On March 1, 2023, we granted, under our 2020 Plan (as defined below), an option to purchase 35,000 shares of our common stock to Dr. Werner and an option to purchase 15,000 shares of our common stock to Mr. Frattaroli, both of which are subject to time-based vesting. One third of each such option award will vest and become exercisable on March 1, 2024, and the remaining portion will vest and become exercisable in 24 equal monthly installments thereafter (commencing with April 1, 2024), subject generally to the relevant named executive officer’s continued service through each vesting date.

Also, on March 1, 2023, we granted, under our 2020 Plan, an option to purchase 17,500 shares of our common stock to Dr. Werner and an option to purchase 7,500 shares of our common stock to Mr. Frattaroli, both of which are subject to performance-based vesting.

The performance based criteria for vesting may include a number of factors such as the successful progression of clinical trials, pre-clinical trials, and development, the successful submission of regulatory filings, the discovery and development of additional candidate molecules, the entering into of one or more strategic partnerships, the adequacy of the Company’s working capital, investor relations and successful organizational growth.

As noted above, in connection with Mr. Frattaroli’s planned retirement on March 31, 2024, the compensation committee of our board of directors has authorized the extension of the exercise period for each of Mr. Frattaroli’s vested option awards subject to time-based vesting until the original expiration date of each of such option award.

Other Benefits

We maintain a Simple IRA retirement savings plan for the benefit of our employees, including our named executive officers, who satisfy certain eligibility requirements. Under the Simple IRA retirement savings plan, eligible employees may elect to defer a portion of their compensation, within the limits prescribed by the Code, on a pre-tax basis through contributions to the Simple IRA retirement savings plan. The Simple IRA retirement savings plan authorizes employer safe harbor matching contributions equal to 3% of covered compensation for eligible employees. The Simple IRA retirement savings plan is intended to qualify under Sections 401(a) and 501(a) of the Code. As a tax-qualified retirement program, contributions to the Simple IRA retirement savings plan and the earnings on those contributions are not taxable to the employees until distributed from the Simple IRA retirement savings plan.

Our named executive officers who are full time employees are eligible to participate in our medical and dental insurance plans on the same basis as our other eligible employees and with the Company paying for 90% of the premiums due for participation in those plans, and with the remainder paid by the eligible employee. In addition, it is the Company’s practice to reimburse Dr. Werner \$418.76 per month in respect of premiums that he pays on his life insurance policy. The Company also paid Dr. Werner \$12,084 in 2023 and 2022 respectively for his automobile expenses.

Director Compensation

The following table presents the total compensation received by each of our non-employee directors during the year ended December 31, 2023.

Name	Fees Earned or Paid in	Option Awards	Total (\$)
	Cash (\$)	(\$)(1)	
Mr. Dennis Berman ⁽²⁾	58,000	16,854	74,854
Dr. Roy Freeman ⁽³⁾	49,000	16,854	65,854
Dr. Paul Grint ⁽⁴⁾	64,000	16,854	80,854
Ms. Gisele Dion ⁽⁵⁾	65,000	16,854	81,854

- (1) The amounts disclosed represent the aggregate grant date fair value of the award as calculated in accordance with FASB Accounting Standards Codification Topic 718, or ASC 718. The calculation of the grant date fair value of the awards disclosed in this column includes a risk-free interest rate of 4.22%, expected volatility of 98.13%, expected term of 4 years and an expected dividend yield of 0%. These amounts do not correspond to the actual value that may be recognized by the directors upon vesting of the applicable awards.
- (2) The aggregate number of shares of our common stock underlying stock options granted to Mr. Berman as of December 31, 2023, was 40,106.
- (3) The aggregate number of shares of our common stock underlying stock options granted to Dr. Freeman as of December 31, 2023, was 40,106.
- (4) The aggregate number of shares of our common stock underlying stock options granted to Dr. Grint as of December 31, 2023, was 40,106.
- (5) The aggregate number of shares of our common stock underlying stock options granted to Ms. Dion as of December 31, 2023, was 16,667.

Our board of directors has approved the following compensation program for our non-employee directors, which became effective upon conclusion of the December 2020 initial public offering. Each non-employee director is eligible to receive compensation for his or her service consisting of annual cash retainers and equity awards as described below. Our board of directors may revise non-employee director compensation as it deems necessary or appropriate.

Cash Compensation

All non-employee directors are entitled to receive the following cash compensation for their services:

- \$40,000 per year for service as a board member;
- \$30,000 per year additionally for service as non-executive Chairperson of the Board;
- \$20,000 per year additionally for service as chair of the audit committee;
- \$10,000 per year additionally for service as member of the audit committee (excluding committee chair);
- \$10,000 per year additionally for service as chair of the compensation committee;
- \$5,000 per year additionally for service as member of the compensation committee (excluding committee chair);
- \$8,000 per year additionally for service as chair of the corporate governance and nominating committee; and
- \$4,000 per year additionally for service as member of the corporate governance and nominating committee (excluding committee chair).

All cash payments to non-employee directors who served in the relevant capacity at any point during the immediately preceding prior fiscal quarter will be paid quarterly in arrears. A non-employee director who served in the relevant capacity during only a portion of the prior fiscal quarter will receive a pro-rated payment of the quarterly payment of the applicable cash retainer.

Equity Compensation

Each new non-employee director is granted an option award to purchase 10,000 shares of our common stock, with 50% of such option award vesting on each of the first two anniversaries of the date of grant, and each current non-employee director is granted an annual option award to purchase 6,667 shares of our common stock, with vesting occurring in full on the earlier of (i) the one year anniversary of the date of grant and (ii) the day prior to the next annual meeting of stockholders. All vesting is subject to the non-employee director's continued service on our board of directors.

On June 30, 2023, we granted to each non-employee director an option award to purchase 6,667 shares of our common stock, which option awards will vest in full on the earlier of (i) the one year anniversary of the date of grant and (ii) the day prior to the next annual meeting of stockholders, subject to the non-employee director's continued service on our board of directors through that date. The Company intends to continue to make annual equity grants to non-employee directors coincident with each annual meeting of stockholders.

Scientific Advisory Board Compensation

With the exception of Drs. Ted and Valina Dawson, each member of our scientific advisory board earns \$400-600 per hour for his or her service as a member of our scientific advisory board. We also reimburse each member of our scientific advisory board for all reasonable and necessary expenses in connection with the performance of his or her services. Members of the scientific advisory board who are also our employees or directors receive no additional compensation for their service on the scientific advisory board.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The following table sets forth the beneficial ownership of our common stock as of March 1, 2024 by:

- each person, or group of affiliated persons, who is known by us to beneficially own more than 5% of our common stock;
- each of the named executive officers;
- each of our directors; and
- all of our current executive officers and directors as a group.

We have determined beneficial ownership in accordance with the rules of the SEC, and thus it represents sole or shared voting or investment power with respect to our securities. Unless otherwise indicated below, to our knowledge, the persons and entities named in the table have sole voting and sole investment power with respect to all shares that they beneficially owned, subject to community property laws where applicable. The information does not necessarily indicate beneficial ownership for any other purpose, including for purposes of Sections 13(d) and 13(g) of the Exchange Act.

We have based our calculation of the percentage of beneficial ownership on 6,476,844 shares of our common stock outstanding on March 1, 2024. We have deemed shares of our common stock subject to stock options that are currently exercisable or exercisable within 60 days of March 1, 2024, to be outstanding and to be beneficially owned by the person holding the stock option for the purpose of computing the percentage ownership of that person. We did not deem these shares outstanding, however, for the purpose of computing the percentage ownership of any other person. Unless otherwise indicated, the address of each beneficial owner listed in the table below is c/o Inhibikase Therapeutics, Inc., 3350 Riverwood Parkway SE, Suite 1900, Atlanta, GA 30339.

Name of Beneficial Owner	Shares Beneficially Owned	
	Shares	Percentage
Named Executive Officers and Directors		
Milton H. Werner, Ph.D. ⁽¹⁾	952,782	14.6%
Joseph Frattaroli, C.P.A. ⁽²⁾	66,682	1.0%
Dennis Berman ⁽³⁾	33,439	*
Roy Freeman, M.D. ⁽⁴⁾	33,439	*
Paul Grint, M.D. ⁽⁵⁾	33,439	*
Gisele Dion ⁽⁶⁾	5,000	*
All executive officers and directors as a group (six-persons)	1,124,781	16.8%
5% Stockholders	—	—

* Represents beneficial ownership of less than one percent.

(1) Consists of (a) 889,242 shares held of record by Milton H. Werner, Ph.D. and (b) 63,540 shares underlying options exercisable within 60 days of March 1, 2024.

(2) Consists of (a) 7,357 shares held of record by Flagship Consulting, Inc., an entity controlled by Mr. Frattaroli, (b) 658 shares held directly and (c) 58,667 underlying options exercisable within 60 days of March 1, 2024.

(3) Consists of 33,439 shares underlying options exercisable within 60 days of March 1, 2024.

(4) Consists of 33,439 shares underlying options exercisable within 60 days of March 1, 2024.

(5) Consists of 33,439 shares underlying options exercisable within 60 days of March 1, 2024.

(6) Consists of 5,000 shares underlying options exercisable within 60 days of March 1, 2024.

Equity Compensation Plan Information

The table below sets forth information with respect to compensation plans under which equity securities of the Company are authorized for issuance as of December 31, 2023:

Plan Category	Number of Securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Securities available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity Compensation Plans approved by stockholders			
Stock Options	839,523	\$ 12.04	1,127,245
Warrants	2,266,133	\$ 7.64	—
Equity Compensation Plans not approved by stockholders	—	—	—

We maintain the 2020 Plan, a stock option plan, which was initially approved by our stockholders on July 21, 2020 and which became effective immediately prior to our December 2020 initial public offering. Employees, officers, directors, consultants and advisors are eligible to participate in the 2020 Plan. As of December 31, 2023, there were 1,127,245 shares reserved for issuance under the 2020 Plan that remained available. Prior to our December 2020 initial public offering we maintained the Company's Equity Incentive Plan (the "2011 Plan"). We ceased making new grants under the 2011 Plan upon effectiveness of the 2020 Plan. However, options that were previously granted under the 2011 Plan will remain subject to the terms and conditions contained in that plan.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

In addition to the compensation arrangements, including employment, termination of employment and change in control arrangements, with our directors and executive officers, including those discussed in the sections titled "Directors, Executive Officers and Corporate Governance" and "Executive Compensation," the following is a description of each transaction since January 1, 2022 or any currently proposed transaction in which:

- we have been or are to be a party to;
- the amount involved exceeded or exceeds \$120,000 or 1% of the average of our total assets as of the end of the last two completed fiscal years; and
- any of our directors, executive officers or holders of more than 5% of our outstanding capital stock, or any immediate family member of, or person sharing the household with, any of these individuals or entities, had or will have a direct or indirect material interest.

For information on our compensation arrangements, including employment, termination of employment and change in control arrangements, with our directors and executive officers, see the sections titled "Directors, Executive Officers and Corporate Governance" and "Executive Compensation."

Indemnification Agreements

We entered into separate indemnification agreements with each of our directors and executive officers, in addition to the indemnification that will be provided for in our amended and restated certificate of incorporation and amended and restated bylaws. The indemnification agreements and our amended restated certificate of incorporation and amended and restated bylaws that became effective upon the completion of December 2020 initial public offering require us to indemnify our directors, executive officers and certain controlling persons to the fullest extent permitted by Delaware law. See the section titled "Executive Compensation — Limitation of Liability and Indemnification" for additional information.

Director Independence

Our common stock is listed on The Nasdaq Capital Market, or Nasdaq. Under the rules of Nasdaq, independent directors must comprise a majority of a listed company's board of directors within one year of the completion of its December 2020 initial public offering. In addition, the rules of Nasdaq require that, subject to specified exceptions, each member of a listed company's audit, compensation and corporate governance and nominating committees be independent. Audit committee members and compensation committee members must also satisfy the independence criteria set forth in Rule 10A-3 and Rule 10C-1, respectively, under the Exchange Act. Under the rules of Nasdaq, a director will only qualify as an "independent director" if, in the opinion of that company's board of directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director.

To be considered to be independent for purposes of Rule 10A-3 and under the rules of Nasdaq, a member of an audit committee of a listed company may not, other than in his or her capacity as a member of the audit committee, the board of directors, or any other board of directors committee: (1) accept, directly or indirectly, any consulting, advisory, or other compensatory fee from the listed company or any of its subsidiaries; or (2) be an affiliated person of the listed company or any of its subsidiaries.

To be considered independent for purposes of Rule 10C-1 and under the rules of Nasdaq, the board of directors must affirmatively determine that each member of the compensation committee is independent, including a consideration of all factors specifically relevant to determining whether the director has a relationship to the company which is material to that director's ability to be independent from management in connection with the duties of a compensation committee member, including, but not limited to: (i) the source of compensation of such director, including any consulting, advisory or other compensatory fee paid by the company to such director; and (ii) whether such director is affiliated with the company, a subsidiary of the company or an affiliate of a subsidiary of the company.

Our board of directors undertook a review of its composition, the composition of its committees and the independence of our directors and considered whether any director has a material relationship with us that could compromise his or her ability to exercise independent judgment in carrying out his or her responsibilities. Based upon information requested from and provided by each non-employee director concerning his or her background, employment and affiliations, including family relationships, our board of directors has determined that none of our directors have relationships that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director and that each of these directors is "independent" as that term is defined under the rules of Nasdaq and Rule 10A-3 and Rule 10C-1 under the Exchange Act. Only Dr. Werner is not independent under Nasdaq's independence standards.

In making these determinations, our board of directors considered the current and prior relationships that each non-employee director has with our company and all other facts and circumstances our board of directors deemed relevant in determining their independence, including the beneficial ownership of our capital stock by each non-employee director, and the transactions involving them described in the section titled "Certain Relationships and Related Party Transactions."

Item 14. Principal Accountant Fees and Services.

The following table sets forth the aggregate fees billed by CohnReznick LLP in connection with audit and other services rendered during the past two fiscal years.

	December 31,	
	2023	2022
Audit Fees (1)	\$ 259,927	\$ 238,900
Audit-Related Fees (2)	—	40,145
Tax Fees (3)	42,685	23,000
	<u>\$ 302,612</u>	<u>\$ 302,045</u>

- (1) Audit fees in 2023 and 2022 include fees related to the annual audit of the Company's financial statements, the review of the interim financial statements included in our quarterly reports on Form 10-Q, and comfort letters, consents and assistance with and review of documents filed with the SEC.
- (2) Audit related fees represent fees for professional services rendered during 2022 in connection with our 2019 NIH grants program ("Yellow Book") audit. Audit related fees represent fees for professional services rendered during 2022 in connection with our 2021 and 2020 Yellow Book audits.
- (3) Tax fees are related to tax compliance, tax advice and tax planning services, including the review and preparation of our federal and state income tax returns.

The Audit Committee pre-approved all services described above in accordance with the pre-approval policies and procedures described below.

INDEX TO FINANCIAL STATEMENTS

	<u>Page</u>
Report of Independent Registered Public Accounting Firm (PCAOB #596)	F-2
Consolidated Balance Sheets as of December 31, 2023 and 2022	F-3
Consolidated Statements of Operations and Comprehensive Loss for the years ended December 31, 2023 and 2022	F-4
Consolidated Statements of Stockholders' Equity for the years ended December 31, 2023 and 2022	F-5
Consolidated Statements of Cash Flows for the years ended December 31, 2023 and 2022	F-6
Notes to Consolidated Financial Statements	F-7

Report of Independent Registered Public Accounting Firm

Board of Directors and Stockholders of Inhibikase Therapeutics, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Inhibikase Therapeutics, Inc. and Subsidiary (the “Company”) as of December 31, 2023 and 2022, and the related consolidated statements of operations and comprehensive loss, stockholders equity, and cash flows for the years then ended and the related notes (collectively referred to as the “consolidated financial statements”). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2023 and 2022, and the results of its operations and its cash flows for each of the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has suffered recurring losses from operations, generated negative cash flows from operating activities and has an accumulated deficit that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (“PCAOB”) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ CohnReznick LLP

We have served as the Company’s auditor since 2018.

Holmdel, New Jersey

March 27, 2024

Inhibikase Therapeutics, Inc.
Consolidated Balance Sheets

	December 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	\$ 9,165,179	\$ 7,188,553
Marketable securities	4,086,873	15,861,620
Accounts receivable	-	39,881
Prepaid research and development	219,817	1,117,616
Prepaid expenses and other current assets	739,179	163,452
Total current assets	14,211,048	24,371,122
Equipment and improvements, net	73,372	236,532
Right-of-use asset	222,227	328,643
Total assets	<u>\$ 14,506,647</u>	<u>\$ 24,936,297</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 646,767	\$ 1,151,173
Lease obligation, current	150,095	145,836
Accrued expenses and other current liabilities	2,259,955	2,398,436
Insurance premium financing payable	381,784	—
Total current liabilities	3,438,601	3,695,445
Lease obligations, net of current portion	90,124	205,451
Total liabilities	<u>3,528,725</u>	<u>3,900,896</u>
Commitments and contingencies (see Note 14)		
Stockholders' equity:		
Preferred stock, \$0.001 par value; 10,000,000 shares authorized at December 31, 2023 and 2022; 0 shares issued and outstanding at December 31, 2023 and 2022	—	—
Common stock, \$0.001 par value; 100,000,000 shares authorized; 6,186,280 and 4,224,294 shares issued and outstanding at December 31, 2023 and 2022	6,186	4,224
Additional paid-in capital	77,871,584	68,798,301
Accumulated other comprehensive income	877	104,718
Accumulated deficit	(66,900,725)	(47,871,842)
Total stockholders' equity	10,977,922	21,035,401
Total liabilities and stockholders' equity	<u>\$ 14,506,647</u>	<u>\$ 24,936,297</u>

See accompanying notes to consolidated financial statements.

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

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

See accompanying notes to consolidated financial statements.

Inhibikase Therapeutics, Inc.
Consolidated Statements of Stockholders' Equity

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2021	4,212,317	\$ 4,212	\$ 68,229,024	\$ —	\$ (29,817,687)	\$ 38,415,549
Stock-based compensation expense	—	—	458,147	—	—	458,147
Issuance of common stock, pre-funded warrants and warrants, net of issuance costs	11,977	12	111,130	—	—	111,142
Other comprehensive income				104,718		104,718
Net loss	—	—	—	—	(18,054,155)	(18,054,155)
Balance at December 31, 2022	4,224,294	4,224	68,798,301	104,718	(47,871,842)	21,035,401
Stock-based compensation expense	—	—	500,148	—	—	500,148
Issuance of common stock, pre-funded warrants and warrants, net of issuance costs	1,961,986	1,962	8,573,135	—	—	8,575,097
Other comprehensive loss				(103,841)	—	(103,841)
Net loss	—	—	—	—	(19,028,883)	(19,028,883)
Balance at December 31, 2023	<u>6,186,280</u>	<u>\$ 6,186</u>	<u>\$ 77,871,584</u>	<u>\$ 877</u>	<u>\$ (66,900,725)</u>	<u>\$ 10,977,922</u>

See accompanying notes to consolidated financial statements.

Inhibikase Therapeutics, Inc.
Consolidated Statements of Cash Flows

	Year ended December 31,	
	2023	2022
Cash flows from operating activities		
Net loss	\$ (19,028,883)	\$ (18,054,155)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	177,398	6,723
Stock-based compensation expense	500,148	458,147
Non-cash consulting and marketing fees	31,536	67,000
Changes in operating assets and liabilities:		
Accounts receivable	39,881	70,258
Operating lease right-of-use assets	106,416	38,055
Prepaid expenses and other assets	(55,387)	1,339,273
Prepaid research and development	897,803	(1,010,616)
Accounts payable	(504,406)	61,395
Operating lease liabilities	(111,068)	(9,859)
Accrued expenses and other current liabilities	(138,481)	(317,324)
Net cash used in operating activities	<u>(18,085,043)</u>	<u>(17,351,103)</u>
Cash flows from investing activities		
Purchases of equipment and improvements	(14,238)	(243,255)
Purchases of investments - marketable securities	(29,426,101)	(20,725,462)
Maturities of investments - marketable securities	41,097,005	4,963,009
Net cash provided by (used in) investing activities	<u>11,656,666</u>	<u>(16,005,708)</u>
Cash flows from financing activities		
Issuance of common stock from exercise of stock options	—	44,142
Deferred offering costs	(138,556)	—
Proceeds from issuance of common stock, pre-funded warrants and warrants, net of issuance costs	8,543,559	—
Repayments of note payable	—	(248,911)
Net cash provided by (used in) financing activities	<u>8,405,003</u>	<u>(204,769)</u>
Net increase (decrease) in cash and cash equivalents	1,976,626	(33,561,580)
Cash and cash equivalents at beginning of year	7,188,553	40,750,133
Cash and cash equivalents at end of year	<u>\$ 9,165,179</u>	<u>\$ 7,188,553</u>
Supplemental disclosures of cash flow information		
Cash paid for interest	\$ —	\$ 973
Insurance premium financing	\$ 381,784	\$ —
Issuance costs	\$ 1,456,479	
Cash paid for amounts included in the measurement of operating lease liabilities	\$ —	\$ 5,553

See accompanying notes to consolidated financial statements.

Inhibikase Therapeutics, Inc.
Notes to Consolidated Financial Statements

1. Nature of Business

We are a clinical-stage pharmaceutical company developing protein kinase inhibitor therapeutics to modify the course of Parkinson's disease ("PD"), Parkinson's-related disorders and other diseases of the Abelson Tyrosine Kinases. The Company's multi-therapeutic pipeline has a primary focus on neurodegeneration and its lead program utilizing Risvodetinib (also known as IKT-148009), a selective inhibitor of the non-receptor Abelson Tyrosine Kinases, targets the treatment of Parkinson's disease inside and outside the brain as well as other diseases that arise from Abelson Tyrosine Kinases. In 2021, we commenced clinical development of Risvodetinib (IKT-148009), which we believe can modify the course of Parkinson's disease including its manifestation in the gastrointestinal tract, or GI. In January 2023, the Company initiated its Phase 2 program, termed 'the 201 trial' (www.the201trial.com), for Risvodetinib (IKT-148009) as a treatment for Parkinson's disease.

We are also developing platform technologies to improve delivery of protein kinase inhibitors in patients. One example of our potential ability to improve drug delivery is IKT-001Pro, a prodrug of the anticancer agent imatinib mesylate, which is intended to treat Stable Phase Chronic Myelogenous Leukemia, or SP-CML. IKT-001Pro has completed a three-part dose finding/dose equivalence study in 66 healthy volunteers (known as 'the 501 trial').

For both IKT-148009 and IKT-001Pro, we have completed clinical batch manufacturing of a film-coated tablet formulation. The bioequivalence studies with IKT-001Pro have already implemented these tablets into the study. A pharmacokinetic bridging study with two different tablet formulations of IKT-148009 was completed in 2023.

Going Concern

The Company has recognized recurring losses. At December 31, 2023, the Company had working capital of \$10,772,447, an accumulated deficit of \$66,900,725, cash and cash equivalents of \$9,165,179, marketable securities of \$4,086,873 and accounts payable and accrued expenses of \$2,906,722.

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 December 2020, June 2021 and January 2023 the Company raised approximately \$14.6 million, \$41.1 million and \$8.5 million in net proceeds for working capital from its initial public offering ("IPO"), June 2021 Offering and January 2023 Offering, 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, general and administrative expenses related to its product candidate programs and negative cash flows from operations. The Company anticipates costs and expenses to increase in the future as the Company continues to develop its product candidates.

The Company may seek to fund its operations 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 December 31, 2023 and funds raised from the February 2024 At the Market Offering is sufficient to fund its normal operations into the first quarter of 2025.

These conditions raise substantial doubt regarding the Company's ability to continue as a going concern for a period of one year after the date the financial statements are issued. Management's plan to alleviate the conditions that raise substantial doubt may include additional equity raises, suspending or delaying certain research projects and capital expenditures and eliminating certain future operating expenses in order to fund operations at reduced levels for the Company to continue as a going concern.

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

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying consolidated financial statements for the years ended December 31, 2023 and 2022, have been prepared in accordance with the rules and regulations of the Securities and Exchange Commission (the “SEC”) and Generally Accepted Accounting Principles in the United States (“U.S. GAAP”) for financial information, which prescribes elimination of all significant inter-company accounts and transactions in the accounts of the Company and its wholly owned subsidiary, IKT Securities Corporation, which was incorporated in the Commonwealth of Massachusetts in December 2021. In the opinion of management, these consolidated financial statements reflect all adjustments which are necessary for a fair statement of the Company’s financial position and results of its operations, as of and for the periods presented. Any reference in these notes to applicable guidance is meant to refer to the authoritative U.S. GAAP as found in the Accounting Standards Codification (“ASC”) and Accounting Standards Updates (“ASU”) of the Financial Accounting Standards Board (“FASB”).

On June 30, 2023, we effected a reverse stock split at the ratio of 1 post-split share for every 6 pre-split shares. All common stock, options, warrant amounts, per share information and references have been retroactively adjusted for all figures presented to reflect this split unless specifically stated otherwise.

Consolidation

The accompanying consolidated financial statements include the Company and its wholly owned subsidiary, IKT Securities Corporation. The Company has eliminated all inter-company transactions for the years presented.

Use of Estimates

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

Off-Balance Sheet Risk and Concentrations of Credit Risk

The Company has no significant off-balance sheet risks, such as foreign exchange contracts, option contracts, or other foreign hedging arrangements. Financial instruments that subject the Company to credit risk primarily consist of cash and cash equivalents. The Company maintains deposits in federally insured financial institutions in excess of federally insured limits. The Company is exposed to credit risk in the event of a default by the financial institutions holding its cash to the extent recorded on the consolidated balance sheets.

The Company has not experienced any losses in such accounts and management believes that the Company does not have significant credit risk with respect to such cash and cash equivalents and marketable securities.

For the years ended December 31, 2023 and 2022, the Company derived 100% of its total revenue from a single source, the United States Government, in the form of federal research grants.

Cash and cash equivalents

The Company considers all highly liquid investments that are readily convertible to known amounts of cash with original maturities of three months or less at date of purchase to be cash equivalents. The Company had cash and cash equivalents of \$9.17 million and \$7.19 million at December 31, 2023 and 2022, respectively.

Accounts receivable

The Company makes judgments as to its ability to collect outstanding receivables and provides an allowance for receivables when collection becomes doubtful. Provisions are made based upon a specific review of all significant outstanding invoices and the overall quality and age of those invoices. To date, the Company has not had any write-offs of bad debt, and the Company did not have an allowance for doubtful accounts as of December 31, 2023 and 2022.

Leases

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

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

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

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

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

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

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

Equipment and Improvements

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

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

Fair Value Measurements

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

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

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

Marketable Securities

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

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

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

Research and Development Costs

Costs incurred in the research and development of the Company's product candidates are expensed as incurred. Research and development expenses consist of costs incurred in performing research and development activities, including activities associated with performing services under grant revenue contracts and include salaries and benefits, stock compensation, research-related subcontractors and consultants, supplies and overhead costs. Advance payments made to suppliers and contract research organizations are classified as prepaid research and development and are expensed as research and development as the supplies are consumed and the contract services are provided. During the years ended December 31, 2023 and 2022 the company incurred expenses of approximately \$33 thousand and \$23 thousand, respectively with a related party vendor included in research and development expenses. As at the years ended December 31, 2023 and 2022 the company had a payable balance with a related party vendor of approximately \$14 thousand and \$16 thousand, respectively included in accounts payable.

Stock-Based Compensation

The Company has a stock-based compensation plan which is more fully described in Note 9. The Company records stock-based compensation for options granted to employees and to members of the board of directors for their services on the board of directors, based on the grant date fair value of awards issued, and the expense is recorded on a straight-line basis over the applicable service period, which is generally one to two years. The Company accounts for non-employee stock-based compensation arrangements based upon the fair value of the consideration received or the equity instruments issued, whichever is more reliably measurable. Stock-based compensation costs for non-employee awards are recognized as services are provided, which is generally the vesting period.

The Company uses the Black-Scholes-Merton option-pricing model to determine the fair value of stock options. The use of the Black-Scholes-Merton option-pricing model requires management to make assumptions with respect to the expected term of the option, the expected volatility of the common stock consistent with the expected life of the option, risk-free interest rates and expected dividend yields of the common stock. The Company has concluded that the historical share option exercise experience does not provide a reasonable basis upon which to estimate expected term. Therefore, the expected term was determined according to the simplified method, which is the average of the vesting tranche dates and the contractual term. Due to the lack of Company specific historical and implied volatility data, we have based our estimate of expected volatility primarily on the historical volatility of a group of similar companies that are publicly traded. For these analyses, companies with comparable characteristics are selected, including enterprise value and position within the industry, and with historical share price information sufficient to meet the expected life of the stock-based awards. The Company computes the historical volatility data using the daily closing prices for the selected companies' shares during the equivalent period of the calculated expected term of its stock-based awards. The risk-free interest rate is determined by reference to U.S. Treasury zero-coupon issues with remaining maturities similar to the expected term of the options. The Company has not paid, and does not anticipate paying, cash dividends on shares of common stock.

Income Taxes

The Company provides for income taxes using the asset and liability method. The Company provides deferred tax assets and liabilities for the expected future tax consequences of temporary differences between the Company's financial statement carrying amounts and the tax bases of assets and liabilities using enacted tax rates expected to be in effect in the years in which the differences are expected to reverse. A valuation allowance is provided to reduce the deferred tax assets to the amount that will more likely than not be realized.

The Company does not have any material uncertain tax positions for which reserves would be required. The Company will recognize interest and penalties related to uncertain tax positions, if any, in income tax expense.

Net Loss Per Share

Basic net loss per share is calculated by dividing net loss applicable to common stockholders by the weighted-average number of shares outstanding during the period, without consideration for common stock equivalents. Diluted net loss per share is calculated by adjusting the weighted-average number of shares outstanding for the dilutive effect of common stock equivalents outstanding for the period, determined using the treasury-stock method. For purposes of the diluted net loss per share calculation, warrants to purchase common stock and stock options are considered to be common stock equivalents, but have been excluded from the calculation of diluted net loss per share, as their effect would be anti-dilutive for all periods presented. Therefore, basic and diluted net loss per share applicable to common stockholders were the same for all periods presented.

Recent Accounting Standards

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.

In June 2016, the FASB issued ASU No. 2016-13, *Measurement of Credit Losses on Financial Instruments* (“ASU 2016-13”). ASU 2016-13 will change how companies account for credit losses for most financial assets and certain other instruments. For trade receivables, loans and held-to-maturity debt securities, companies will be required to recognize an allowance for credit losses rather than reducing the carrying value of the asset. In November 2019, the FASB issued ASU No. 2019-10, *Financial Instruments - Credit Losses (Topic 326), Derivatives and Hedging (Topic 815), and Leases (Topic 842): Effective Dates to amend the effective date of ASU 2016-13*, for entities eligible to be “smaller reporting companies,” as defined by the SEC, to be effective for fiscal years beginning after December 15, 2022, including interim periods within those fiscal years. The Company adopted ASU 2016-13 as of January 1, 2023, on a prospective basis. The adoption did not have a material impact on the Company’s consolidated financial statements.

In August 2020, the FASB issued ASU No. 2020-06, *Debt – Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging – Contracts in Entity’s Own Equity (Subtopic 815-40)* (“ASU 2020-06”). ASU 2020-06 simplifies the accounting for convertible debt instruments by reducing the number of accounting models and the number of embedded features that could be recognized separately from the host contract. Consequently, more convertible debt instruments will be accounted for as a single liability measured at its amortized cost, as long as no other features require bifurcation and recognition as derivatives. ASU 2020-06 also requires use of the if-converted method in the diluted earnings per share calculation for convertible instruments. ASU 2020-06 is effective for fiscal years beginning after December 15, 2023, and interim periods within those fiscal years for smaller reporting companies, with early adoption permitted. The Company adopted ASU 2020-06 as of January 1, 2023, on a prospective basis. The adoption did not have a material impact on the Company’s consolidated financial statements.

Accounting Standards Issued, Not Yet Adopted

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

3. Supplemental Balance Sheet Information

Accrued expenses and other current liabilities consist of the following:

	December 31, 2023	December 31, 2022
Accrued consulting	\$ 49,395	\$ 232,390
Accrued compensation	635,451	459,997
Accrued research and development	1,472,292	1,696,129
Accrued other	102,817	9,920
Total accrued expenses and other current liabilities	<u>\$ 2,259,955</u>	<u>\$ 2,398,436</u>

4. Fair Value of Financial Instruments

The following table summarizes cash equivalents and marketable securities measured at their fair value on a recurring basis as of:

	Fair Value Measurements as of December 31, 2023 Using:			
	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	\$ 8,039,024	\$ —	\$ —	\$ 8,039,024
Total	\$ 8,039,024	\$ —	\$ —	\$ 8,039,024

Marketable securities, available-for-sale:				
U.S. treasury obligations	\$ 4,086,873	\$ —	\$ —	\$ 4,086,873
Total	\$ 4,086,873	\$ —	\$ —	\$ 4,086,873

	Fair Value Measurements as of December 31, 2022 Using:			
	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	\$ 5,304,405	\$ —	\$ —	\$ 5,304,405
Total	\$ 5,304,405	\$ —	\$ —	\$ 5,304,405

Marketable securities, available-for-sale:				
U.S. treasury obligations	\$ 15,861,620	\$ —	\$ —	\$ 15,861,620
Total	\$ 15,861,620	\$ —	\$ —	\$ 15,861,620

5. Marketable Securities

Marketable securities consisted of the following:

December 31, 2023	Amortized Cost	Unrealized Gain	Unrealized Loss	Fair Value
Marketable securities, available-for-sale:				
U.S. treasury obligations	\$ 4,085,996	\$ 877	\$ —	\$ 4,086,873
Total	\$ 4,085,996	\$ 877	\$ —	\$ 4,086,873
December 31, 2022	Amortized Cost	Unrealized Gain	Unrealized Loss	Fair Value
Marketable securities, available-for-sale:				
U.S. treasury obligations	\$ 15,756,902	\$ 104,718	\$ —	\$ 15,861,620
Total	\$ 15,756,902	\$ 104,718	\$ —	\$ 15,861,620

As of December 31, 2023, the Company held three U.S. Treasury debt securities that were in an unrealized gain position totaling \$877. As of December 31, 2022, the Company held three U.S. Treasury debt securities that were in an unrealized gain position totaling \$104,718. All U.S. treasury obligations were due to mature in less than one year for the years ended December 31, 2023 and 2022, respectively.

The Company received proceeds of \$41.1 million from maturities of marketable securities for the year ended December 31, 2023. The Company received proceeds of \$4.96 million from maturities of marketable securities for the year ended December 31, 2022.

6. Equipment and Improvements

Equipment and Improvements, net

	Year ended December 31,	
	2023	2022
Furniture and office equipment	\$ 86,930	\$ 72,692
Lab equipment	—	153,668
IT equipment	16,895	16,895
	103,825	243,255
Less: accumulated depreciation	30,453	6,723
Total	<u>\$ 73,372</u>	<u>\$ 236,532</u>

Depreciation expense for the year ended December 31, 2023 was \$177,398. Depreciation expense for the year ended December 31, 2022 was \$6,723.

7. Insurance Premium Financing Payable

	Year ended December 31,	
	2023	2022
AON	\$ 381,784	\$ —
Total insurance premium financing payable	<u>\$ 381,784</u>	<u>\$ —</u>

Future principal payments on the insurance premium financing payable as of December 31, 2023, are as follows:

Year ended December 31,	
2024	\$ 381,784
Total payable	<u>\$ 381,784</u>

Insurance premium financing Payable to AON

In December 2023, the Company entered into an insurance premium financing and security agreement with AON Premium Finance, LLC ("AON"). Under the agreement, the Company financed \$381,784 of certain premiums at an 8.59% annual interest rate. As of December 31, 2023, the outstanding principal of the loan was \$381,784 and is included on the balance sheet in Insurance premium financing payable. The final payment is due in December 2024.

8. Stockholders' Equity

Each share of common stock is entitled to one vote. The holders of common stock are also entitled to receive dividends whenever funds are legally available and when declared by the board of directors, subject to the prior rights of holders of all classes of stock outstanding. As of December 31, 2023, a total 1,127,245 shares of common stock were reserved for issuance upon the exercise of outstanding stock options and warrants under the 2020 Equity Incentive Plan and the 2011 Equity Incentive Plan.

Share Issuances

On January 25, 2023, the Company entered into a securities purchase agreement in connection with a registered direct offering and concurrent private placement with an institutional investor. The Company also entered into a securities purchase agreement and a registration rights agreement in connection with a concurrent private placement with the same institutional investor (collectively the "January 2023 Offering"). The January 2023 Offering consisted of (i) 466,799 shares of Common Stock sold at \$5.16 per share, (ii) Common Warrants to purchase up to 1,937,985 shares of Common Stock with an exercise price of \$5.16, and (iii) Pre-Funded Warrants to purchase up to 1,471,187 shares of Common Stock with an exercise price of \$0.06, all issued to Armistice Capital Master Fund Ltd ("Armistice"). The warrants will expire on January 27, 2028. As part of the January 2023 Offering, the Company further issued warrants to H.C. Wainwright & Co., LLC ("Placement Agent Warrants") to purchase up to 67,830 shares of Common Stock with an exercise price of \$6.45 and an expiration date of January 25, 2028. As of December 31, 2023 the institutional investor has exercised all 1,471,187 Pre-Funded Warrants.

The Company received net proceeds from the January 2023 Offering of approximately \$8.5 million. Effective January 25, 2023, the Company terminated the Equity Distribution Agreement with Piper Sandler & Co. by providing a notice of termination in accordance with the terms of the Equity Distribution Agreement (see Note 10).

In September 2023 and December 2023, the Company issued 12,000 shares respectively of its stock in exchange for digital media consulting services. The fair value of the stock was \$17,280 and \$14,280 respectively based upon the closing price of the shares on the date of the transaction. Issuance costs were not material. No additional rights or options were granted to this accredited investor in connection with this issuance. This issuance is exempt from registration pursuant to Section 4(a)(2) of the Securities Act as transactions by an issuer not involving any public offering.

In January 2022, the Company issued 3,643 shares of its common stock in connection with the exercise of non-qualified stock options with a strike price of \$12.12 per share. Issuance costs were not material. No additional rights or options were granted to this accredited investor in connection with this issuance. This issuance was exempt from registration pursuant to Section 4(a)(2) of the Securities Act as transactions by an issuer not involving any public offering.

In February 2022, a corporate accredited investor subscribed for, and the Company issued, 8,334 shares of its common stock in exchange for consulting services. The fair value of the common stock was \$67,000 based upon the closing price of the shares on the date of the transaction. Issuance costs were not material. No additional rights or options were granted to this accredited investor in connection with this issuance. This issuance was exempt from registration pursuant to Section 4(a)(2) of the Securities Act as transactions by an issuer not involving any public offering.

9. Stock-Based Compensation

2020 Equity Incentive Plan

On July 21, 2020, the Company's board of directors and its stockholders approved the 2020 Equity Incentive Plan (the "2020 Plan"). The 2020 Plan became effective immediately prior to the closing of the Company's December 2020 IPO. The 2020 Plan provides for the granting of incentive stock options, nonqualified stock options, stock appreciation rights, restricted stock or restricted stock units to any of its employees, directors, consultants and other service providers or those of its affiliates. The board of directors has initially designated the compensation committee to administer the 2020 Plan. The compensation committee has broad authority to administer the plan and to determine the vesting conditions for awards. Neither the compensation committee nor the board of directors are authorized to reprice outstanding options or stock appreciation rights without shareholder consent. In addition, any amendments to increase the total number of shares reserved for issuance under the 2020 Plan or modification of the classes of participants eligible to awards requires ratification by the stockholders. Subject to certain adjustments, the maximum number of shares of common stock that may be issued under the 2020 Plan in connection with awards is limited to 1,441,667 shares.

Following the effectiveness of the 2020 Plan, the Company ceased making grants under the 2011 Plan. However, the 2011 Plan continues to govern the terms and conditions of the outstanding awards granted under the 2011 Plan. Shares of common stock subject to awards granted under the 2011 Plan that cease to be subject to such awards by forfeiture or otherwise after the effective date of the 2020 Plan will become available for issuance under the 2020 Plan.

2011 Equity Incentive Plan

Prior to the closing of its IPO, the Company maintained the 2011 Plan, pursuant to which the Company made grants of non-qualified stock options to eligible employees and other service providers.

Stock Options

During the years ended December 31, 2023 and 2022, the Company granted options with an aggregate fair value of \$338,738 and \$536,965, respectively, which are being amortized to expense over the vesting period of the options as the services are being provided.

The following is a summary of option activity under the 2011 Plan and the 2020 Plan:

	Number of Shares	Weighted- Average Exercise Price Per Share	Weighted- Average Remaining Contractual Term (In Years)
Outstanding at December 31, 2021	609,895	\$ 14.58	6.99
Granted	144,982	6.00	—
Exercised	(3,643)	12.12	—
Forfeited	(18,839)	7.68	—
Cancelled	—	—	—
Outstanding at December 31, 2022	732,395	13.14	6.20
Granted	111,668	3.03	—
Exercised	—	—	—
Forfeited	(4,540)	10.74	—
Cancelled	—	—	—
Outstanding at December 31, 2023	<u>839,523</u>	<u>11.90</u>	<u>5.30</u>
Exercisable at December 31, 2023	<u>648,979</u>	<u>13.91</u>	<u>5.13</u>

As of December 31, 2023, the intrinsic value of options outstanding was \$0.0 million and 100% of the intrinsic value of options was exercisable. Intrinsic value is calculated based on the aggregate difference between the closing price of the Company's common stock on the last trading day of 2023 and the exercise price of each in the money stock option award. We adjust for actual forfeitures as they occur.

There were no options to purchase stock that vested upon the achievement of performance conditions at December 31, 2023 or December 31, 2022.

The weighted-average fair values of options granted in the years ended December 31, 2023 and 2022 were \$3.03 and \$3.84, per share, respectively, and were calculated using the following estimated assumptions:

	Year ended December 31,	
	2023	2022
Weighted-average risk-free interest rate	4.27%	2.17%
Expected dividend yield	0.00%	0.00%
Expected volatility	98.45%	84.88%
Expected terms	4.38 years	4.39 years

The total fair values of stock options that vested during the years ended December 31, 2023 and 2022 were \$608,539 and \$618,157, respectively.

As of December 31, 2023, there was \$173,738 of total unrecognized compensation cost related to non-vested stock options granted under the 2011 Plan and the 2020 Plan. The Company expects to recognize that cost over a remaining weighted-average period of 2.37 years as of December 31, 2023.

Restricted Stock Units

During the years ended December 31, 2023 and 2022, there were no restricted stock units issued or outstanding.

Stock-Based Compensation Expense

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

	Year ended December 31,	
	2023	2022
Research and development	\$ 160,080	\$ 120,671
Selling, general and administrative	340,068	337,476
Total stock-based compensation expense	<u>\$ 500,148</u>	<u>\$ 458,147</u>

10. ATM Program

On May 16, 2022, the Company entered into an Equity Distribution Agreement (the “Piper Agreement”) with Piper Sandler & Co. as sales agent (the “Agent”), pursuant to which the Company may, from time to time, issue and sell shares of its common stock, at an aggregate offering price of up to \$9.8 million (the “Shares”) through the Agent. Under the terms of the Agreement, the Agent may sell the Shares at market prices by any method that is deemed to be an “ATM” as defined in Rule 415 under the Securities Act, as amended.

Subject to the terms and conditions of the Agreement, the Agent will use its commercially reasonable efforts to sell the Shares from time to time, based upon the Company’s instructions. The Company has no obligation to sell any of the Shares, and may at any time suspend sales under the Agreement or terminate the Agreement in accordance with its terms. The Company has provided the Agent with customary indemnification rights, and the Agent will be entitled to a fixed commission of 3.0% of the aggregate gross proceeds from the Shares sold. The Agreement contains customary representations and warranties, and the Company is required to deliver customary closing documents and certificates in connection with sales of the Shares. As of December 31, 2022, no Shares have been sold under the Agreement.

Effective January 25, 2023, the Company terminated the Piper Agreement by providing a notice of termination to the Agent in accordance with the terms of the Equity Distribution Agreement.

11. Warrants

On January 25, 2023, the Company entered into a securities purchase agreement in connection with a registered direct offering and concurrent private placement with an institutional investor. The Company also entered into a securities purchase agreement and a registration rights agreement in connection with a concurrent private placement with the same institutional investor (collectively the “January 2023 Offering”). The January 2023 Offering consisted of (i) 466,799 shares of Common Stock sold at \$5.16 per share, (ii) Common Warrants to purchase up to 1,937,985 shares of Common Stock with an exercise price of \$5.16, and (iii) Pre-Funded Warrants to purchase up to 1,471,187 shares of Common Stock with an exercise price of \$0.06, all issued to Armistice Capital Master Fund Ltd (“Armistice”). The warrants will expire on January 27, 2028. As part of the January 2023 Offering, the Company further issued warrants to H.C. Wainwright & Co., LLC (“Placement Agent Warrants”) to purchase up to 67,830 shares of Common Stock with an exercise price of \$6.45 and an expiration date of January 25, 2028. As of December 31, 2023 the institutional investor has exercised all of their 1,471,187 Pre-Funded Warrants.

No warrants were entered in to or exercised for the year ended December 31, 2022.

12. Net Loss Per Share

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

	Year ended December 31,	
	2023	2022
Numerator:		
Net loss	\$ (19,028,883)	\$ (18,054,155)
Denominator:		
Weighted-average number of common shares outstanding – basic and diluted	5,333,096	4,223,099
Net loss per share applicable to common stockholders – basic and diluted	\$ (3.57)	\$ (4.28)

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:

	Year ended December 31,	
	2023	2022
Options to purchase shares of stock	839,523	732,395
Warrants to purchase shares of stock	2,266,133	260,319
Total	3,105,656	992,714

13. Income Taxes

No provision or benefit for federal or state income taxes has been recorded, as the Company has incurred a net loss for all of the periods presented, and the Company has provided a full valuation allowance against its deferred tax assets.

At December 31, 2023, the Company had federal net operating loss carryforwards of approximately \$1.6 million which will begin to expire in varying amounts annually beginning in 2030 and \$33.1 million of federal net operating losses with no expiration. At December 31, 2023, the Company had state net operating loss carryforwards of approximately \$30.2 million which will begin to expire in varying amounts annually beginning in 2030. Utilization of net operating losses may be subject to substantial annual limitations due to the “change in ownership” provisions of the Internal Revenue Code, and similar state provisions. The annual limitations may result in the expiration of net operating losses & tax credits before utilization. The Company has not yet conducted a study to determine if any such changes, including its 2020 IPO or 2021 underwritten public offering, have occurred that could limit the Company’s ability to use the net operating losses and tax credit carryforwards. As of December 31, 2023, the Company also has federal tax credits of \$1.1 million which begin to expire in 2042.

The reconciliation of the U.S. federal statutory rate to the Company’s effective tax rate is as follows:

	Year Ended December 31,	
	2023	2022
Tax at statutory rate	21.00%	21.00%
State income taxes	5.54%	6.17%
Tax law change	1.37%	—
Stock-based compensation	(0.11)%	—
R&D Tax Credits	5.75%	—
Other	(0.05)%	0.03%
Change in valuation allowance	(33.50)%	(27.20)%
Effective tax rate	<u>0.00%</u>	<u>0.00%</u>

On October 4, 2023, Massachusetts enacted tax law changes which included the adoption of a single sales apportionment factor effective on January 1, 2025. As required under ASC 740, the Company has accounted for the deferred tax impacts of this tax law change in the period the tax law was enacted, which has the impact of increasing its state deferred tax assets. The impact of the tax law change is offset by a change in valuation allowance.

The significant components of the Company’s deferred tax assets consist of the following at December 31, 2023 and 2022:

	December 31,	
	2023	2022
Deferred tax assets:		
Net operating loss carryforwards	\$ 9,179,115	\$ 6,890,275
Capitalized research and development	5,669,202	2,854,530
Stock-based compensation	2,629,771	2,440,885
R&D tax credit carryforwards	1,093,839	—
Accrued expenses	187,393	199,961
Other	1,827	—
Total deferred tax assets	18,761,147	12,385,651
Deferred tax asset valuation allowance	(18,759,181)	(12,385,651)
Total deferred tax asset	<u>\$ 1,966</u>	<u>\$ —</u>
Deferred tax liabilities:		
Fixed Assets	\$ (1,966)	\$ —
Total deferred tax assets	<u>\$ (1,966)</u>	<u>\$ —</u>
Net deferred tax asset (liability)	<u>\$ —</u>	<u>\$ —</u>

The Company has maintained a full valuation allowance against its deferred tax assets in all periods presented. A valuation allowance is required to be recorded when it is not more likely than not that some portion or all of the net deferred tax assets will be realized. Since the Company cannot determine that it is more likely than not that it will generate taxable income, and thereby realize the net deferred tax assets, a full valuation allowance has been provided. The valuation allowance increased \$6.4 million and \$4.9 million for the years ended December 31, 2023 and 2022, respectively. The increases in 2023 and 2022 are primarily related to each year's taxable loss. The Company has no uncertain tax positions at December 31, 2023 and 2022 that would affect its effective tax rate. Since the Company is in a loss carryforward position, the Company is generally subject to U.S. federal and state income tax examinations by tax authorities for all years for which a loss carryforward is available. As of December 31, 2023, the Company was open to examination in the U.S. federal and certain state jurisdictions for all of the Company's tax years since the net operating losses may potentially be utilized in future years to reduce taxable income. Since the Company is in a loss carryforward position, it is generally subject to examination by the U.S. federal, state, and local income tax authorities for all tax years in which a loss carryforward is available.

The Tax Cuts and Jobs Act ("TCJA") resulted in significant changes to the treatment of research and developmental (R&D) expenditures under Section 174. For tax years beginning after Dec. 31, 2021, taxpayers are required to capitalize and amortize all R&D expenditures that are paid or incurred in connection with their trade or business. Specifically, costs for U.S.-based R&D activities must be amortized over five years and costs for foreign R&D activities must be amortized over 15 years—both using a midyear convention. During the year ended December 31, 2023, the Company capitalized for tax purposes \$12.6 million and \$0.7 million of domestic and foreign R&D expenses, respectively.

14. Commitments and Contingencies

Operating Leases

On April 18, 2022, the Company entered into an operating lease agreement for office space at its new location in Lexington, Massachusetts (the "Office Lease"). On August 8, 2022, the Company commenced occupancy of the leased space. The lease runs through September 30, 2025 or a remaining lease period of 1.5 years. We have an option to extend the lease term for an additional three (3) years thereafter.

The Company accounts for the Office Lease under the provisions of ASU No. 2021-09, ASU 2018-10, and ASC 842. We recorded a right-of-use asset and a corresponding operating lease liability on the Company's consolidated balance sheets upon the accounting commencement date in August 2022. The lease liability was measured at the accounting commencement date utilizing 12% which is the Company's incremental borrowing rate. The right-of-use asset had a balance of \$222,227 at December 31, 2023. The operating lease obligations totaled \$240,219 at December 31, 2023, of which \$150,095 is included under current liabilities and \$90,124 is included under non-current liabilities. The Company recorded lease expense relating to the Office Lease of \$141,182 and short-term payments of \$23,281 for the year ended December 31, 2023 and lease expense relating to the Office Lease of \$56,114 and short-term payments of \$58,756 for the year ended December 31, 2022 included in selling, general and administrative expenses.

The Office Lease contains escalating payments during the lease period. Upon execution of the Office Lease, the Company prepaid one month of rent and a security deposit, one of which will be held in escrow and credited at the termination of the lease and the other of which will be applied to the first month's rent. As of December 31, 2023, a security deposit of approximately \$25,000 was included in prepaid expenses and other current assets on the Company's consolidated balance sheets related to the Office Lease.

Future minimum lease payments under these leases at December 31, 2023, are presented by calendar year as follows:

Year		
2024	\$	150,095
2025		114,966
Total lease payments		265,061
Less: imputed interest		(24,842)
Present value of operating lease liabilities	\$	<u>240,219</u>

Guarantees

As permitted under Delaware law, the Company indemnifies its officers and directors for certain events or occurrences while the officer or director is, or was, serving at the Company's request in such capacity. The term of the indemnification is for the officer's or director's lifetime. The maximum potential amount of future payments the Company could be required to make is unlimited; however, the Company has directors' and officers' insurance coverage that limits its exposure and enables it to recover a portion of any future amounts paid.

The Company leases office space on a month-to-month basis. The Company has standard indemnification arrangements under the lease that require it to indemnify the landlord against all costs, expenses, fines, suits, claims, demands, liabilities, and actions directly resulting from any breach, violation or nonperformance of any covenant or condition of the Company's lease.

In the ordinary course of business, the Company enters into indemnification agreements with certain suppliers and business partners where the Company has certain indemnification obligations limited to the costs, expenses, fines, suits, claims, demands, liabilities and actions directly resulting from the Company's gross negligence or willful misconduct, and in certain instances, breaches, violations or nonperformance of covenants or conditions under the agreements.

As of December 31, 2023, and 2022, the Company had not experienced any material losses related to these indemnification obligations, and no material claims with respect thereto were outstanding. The Company does not expect significant claims related to these indemnification obligations and, consequently, concluded that the fair value of these obligations is negligible, and no related reserves were established.

License Agreements

Sphaera Pharma Pte. Ltd.

On March 2, 2012, we entered into a collaborative research and development agreement, or the Sphaera Agreement, with Sphaera Pharma Pte. Ltd., or Sphaera, to collaborate on the development of the prodrug technology to be applied to protein kinase inhibitors for oncology and non-oncology indications. Under the terms of the Sphaera Agreement, each party would retain its pre-existing intellectual property, but any intellectual property conceived or reduced to practice under and certain results arising from the Sphaera Agreement would be assigned to us. On October 5, 2012, we and Sphaera amended the Sphaera Agreement to reflect joint patent applications in the U.S. and India by us and Sphaera for a series of novel compounds. While the underlying intellectual property would be jointly owned, we have the exclusive right to commercialize thirteen of the twenty-four linkers detailed in the filed patent applications, collectively, the Company Compounds, including the linker attached to imatinib that comprises IKT-001Pro, with the remaining nine linkers owned by Sphaera, collectively, the Sphaera Compounds. Sphaera has the right to develop the Company Compounds for oncology indications but may not commercialize the Company Compounds unless we abandon the Company Compounds. We have notified Sphaera that we do not intend to abandon the Company Compounds. We do not currently have the right to develop the Sphaera Compounds. Additionally, if either party files an IND for a Company Compound that has been abandoned by the other party for an oncology indication in humans, the non-filing party is prohibited from developing such Company Compound. In 2023, Sphaera liquidated and transferred its interests to Pivot Holding LLC, a U.S. entity.

The prosecution of patents related to the Company Compounds, which includes the prodrug technology, is the responsibility of the Company.

As consideration for its services, Sphaera has received a fixed fee of \$160,000 and may be entitled to certain milestone payments, none of which have yet to have been reached, and single-digit royalty payments of a percentage of annual net sales and sublicenses were a compound covered by this agreement ever commercialized:

Milestone Event	Payment
First dosing of patient in US Phase 1 trial	\$ 250,000
US Phase 1 trial completion with endpoints met	500,000
US Phase 2 trial completion with endpoints met	875,000
FDA Approval	4,000,000
Total potential milestone payments	<u>\$ 5,625,000</u>

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. We are not currently a party to any material litigation or legal proceedings.

15. Simple Retirement Account for Employees (the "Simple IRA")

The Company established an individual retirement plan for employees effective January 1, 2013 under Section 408(p) of the Internal Revenue Code. The Simple IRA covers substantially all employees of the Company who received at least \$5,000 in compensation from the Company during any two preceding years and are reasonably expected to receive at least \$5,000 in compensation from the Company in the current year of participation. Subject to certain overall statutory limitations, the Company must match employee contributions up to 3% of employees' qualified compensation for the year. Company contributions under the Simple IRA were \$59,511 and \$48,408 for the years ended December 31, 2023 and 2022, respectively.

16. Subsequent Events

On February 1, 2024, the Company entered into an Equity Distribution Agreement (the "Wainwright Agreement") with H.C. Wainwright & Co., LLC as sales agent (the "Agent"), pursuant to which the Company may, from time to time, issue and sell shares of its common stock, at an aggregate offering price of up to approximately \$5.7 million (the "Shares") through the Agent. Under the terms of the Agreement, the Agent may sell the Shares at market prices by any method that is deemed to be an "ATM" as defined in Rule 415 under the Securities Act, as amended.

Subject to the terms and conditions of the Agreement, the Agent will use its commercially reasonable efforts to sell the Shares from time to time, based upon the Company's instructions. The Company has no obligation to sell any of the Shares, and may at any time suspend sales under the Agreement or terminate the Agreement in accordance with its terms. The Company has provided the Agent with customary indemnification rights, and the Agent will be entitled to a fixed commission of 3.0% of the aggregate gross proceeds from the Shares sold. The Agreement contains customary representations and warranties, and the Company is required to deliver customary closing documents and certificates in connection with sales of the Shares. As of the day of this Report, 290,564 Shares have been sold under the Agreement with net proceeds from the Agent of \$777,910 to the Company.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(1) For a list of the financial statements included herein, see Index to the Consolidated Financial Statements on page F-1 of this Annual Report on Form 10-K, incorporated into this Item by reference.

(2) Financial statement schedules have been omitted because they are either not required or not applicable or the information is included in the consolidated financial statements or the notes thereto. Those financial statement schedules required to be filed by Item 8 of this form, and by paragraph (b) below.

(3) The information required by this Item is set forth on the exhibit index of this Annual Report on Form 10-K.

EXHIBIT INDEX

Exhibit Number	Description*	Form	File Number	Where Located		Filed Herewith
				Exhibit Number	Filing Date	
3.1	Amended and Restated Certificate of Incorporation of Inhibikase Therapeutics, Inc.	8-K	001-39676	3.1	12/29/2020	
3.2	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of Inhibikase Therapeutics, Inc.	8-K	001-39676	3.1	6/29/2023	
3.3	Amended and Restated Bylaws of Inhibikase Therapeutics, Inc.	8-K	001-39676	3.2	12/29/2020	
4.1	Specimen common stock Certificate of the Registrant	S-1	333-240036	4.1	07/23/2020	
4.2	Form of Warrant to purchase common stock of the Registrant, issued to each of the members of the Scientific Advisory Board and the investor named in Schedule A thereto	S-1	333-240036	4.2	07/23/2020	
4.3	Warrant, issued by Inhibikase Therapeutics, Inc. to Kubera North America, Inc., dated October 5, 2018	S-1	333-240036	4.3	07/23/2020	
4.4	Warrant, issued by Inhibikase Therapeutics, Inc. to Francis E. McDaniel, dated January 1, 2019	S-1A	333-240036	4.4	09/15/2020	
4.5	Warrant, issued by Inhibikase Therapeutics, Inc. to Francis E. McDaniel, dated March 31, 2020	S-1	333-240036	4.5	07/23/2020	
4.6	Form of Representative's Warrant	S-1	333-240036	4.6	07/23/2020	
4.7	Form of Late IPO Warrant	S-1	333-240036	4.7	07/23/2020	
4.8	Form of Pre-Funded Warrant	8-K	001-39676	4.1	01/26/2023	
4.9	Form of Private Common Warrant	8-K	001-39676	4.2	01/26/2023	
4.10	Form of PIPE Pre-Funded Warrant	8-K	001-39676	4.3	01/26/2023	
4.11	Form of PIPE Common Warrant	8-K	001-39676	4.4	01/26/2023	
4.12	Form of Placement Agent Warrant	8-K	001-39676	4.5	01/26/2023	
10.1	License Agreement, by and between Inhibikase Therapeutics, Inc. and Emory University, dated June 8, 2010	S-1	333-240036	10.1	07/23/2020	
10.2	Collaborative Research and Development Agreement, by and between Inhibikase Therapeutics, Inc. and Sphaera Pharma Pte. Ltd., dated February 29, 2012	S-1	333-240036	10.2	07/23/2020	
10.3	First Amendment to Collaborative Research and Development Agreement, by and between Inhibikase Therapeutics Inc. and Sphaera Pharma Pte. Ltd., dated October 5, 2012	S-1	333-240036	10.3	07/23/2020	
10.4#	2011 Equity Incentive Plan and forms of agreements thereunder	S-1	333-240036	10.4	07/23/2020	
10.5#	2020 Equity Incentive Plan and forms of agreements thereunder	S-1/A	333-240036	10.5	12/04/2020	

10.6#	Employment Agreement, by and between Inhibikase Therapeutics, Inc. and Milton H. Werner, Ph.D., dated April 1, 2014	S-1	333-240036	10.6	07/23/2020	
10.7#	Employment Agreement, by and between Inhibikase Therapeutics, Inc. and Milton H. Werner Ph.D., effective upon the completion of the Company's Initial Public Offering	S-1	333-240036	10.7	07/23/2020	
10.8#	Employment Agreement, by and between Inhibikase Therapeutics, Inc. and Joseph Frattaroli, dated October 24, 2018	S-1	333-240036	10.8	07/23/2020	
10.9	Form of Inhibikase Therapeutics, Inc. Directors and Officers Indemnification Agreement	S-1	333-240036	10.9	07/23/2020	
10.10	Form of Inhibikase Therapeutics, Inc. Subscription Agreement	S-1	333-240036	10.10	07/23/2020	
10.11	Side Letter to Subscription Agreement of Joseph Ventures Allium, LLC, dated July 19, 2018	S-1	333-240036	10.11	07/23/2020	
10.12	Side Letter to Subscription Agreement of Joseph Ventures Allium, LLC, dated August 31, 2018	S-1	333-240036	10.12	07/23/2020	
10.13	Side Letter to Subscription Agreement of Joseph Ventures Allium, LLC, dated June 15, 2018	S-1	333-240036	10.13	07/23/2020	
10.14	Lease Agreement, dated June 5, 2020, by and between Inhibikase Therapeutics, Inc. and Regus Management Group, LLC	S-1	333-240036	10.14	07/23/2020	
10.15	Form of Consulting Agreement	S-1	333-240036	10.15	07/23/2020	
10.16	Form of Representative's Warrant Agreement	8-K	001-39676	4.2	06/16/2021	
10.17#	Amendment dated March 3, 2022 to the Employment Agreement, by and between Inhibikase Therapeutics, Inc. and Milton H. Werner, Ph.D., dated December 28, 2020.	8-K	001-39676	10.1	03/08/2022	
10.18#	Amendment dated March 3, 2022 to the Employment Agreement, by and between Inhibikase Therapeutics, Inc. and Joseph Frattaroli, dated October 24, 2018.	8-K	001-39676	10.2	03/08/2022	
10.19	Form of Stock Option Grant Notice and Award Agreement	8-K	001-39676	10.3	03/08/2022	
10.20#	Form of Director Offer Letter	8-K	001-39676	10.1	09/01/2022	
10.21	Securities Purchase Agreement, dated as of January 25, 2023 (Registered Direct)	8-K	001-39676	10.1	01/26/2023	
10.22	Securities Purchase Agreement, dated as of January 25, 2023 (PIPE)	8-K	001-39676	10.2	01/26/2023	
10.23	Registration Rights Agreement, dated as of January 25, 2023 (PIPE)	8-K	001-39676	10.3	01/26/2023	
10.24	At The Market Offering Agreement, dated February 1, 2024, by and between Inhibikase Therapeutics, Inc. and H.C. Wainwright & Co., LLC.	8-K	001-39676	10.1	02/01/2024	
14.1	Code of Ethics					X
21.1	Subsidiaries of the Registrant	10-K	001-39676	21.1	03/31/2023	
23.1	Consent of Independent Registered Public Accounting Firm.					X
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					X
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					X
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	
97.1	Compensation Clawback Policy	X
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.	X
101.SCH	Inline XBRL Taxonomy Extension Schema Document	X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document	X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document	X
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document	X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document	X
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)	X

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

(*) Certain of the agreements filed as exhibits contain representations and warranties made by the parties thereto. The assertions embodied in such representations and warranties are not necessarily assertions of fact, but a mechanism for the parties to allocate risk. Accordingly, investors should not rely on the representations and warranties as characterizations of the actual state of facts or for any other purpose at the time they were made or otherwise.

(**) Furnished herewith.

Item 16. Form 10-K Summary

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

Company Name

Date: March 27, 2024

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

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Report has been signed below by the following persons on behalf of the Registrant in the capacities and on the dates indicated.

Name	Title	Date
<u> /s/ MILTON H. WERNER, Ph.D. </u> Milton H. Werner, Ph.D.	Chief Executive Officer and Director (<i>Principal Executive Officer</i>)	March 27, 2024
<u> /s/ JOSEPH FRATTAROLI </u> Joseph Frattaroli	Chief Financial Officer (<i>Principal Financial Officer and Principal Accounting Officer</i>)	March 27, 2024
<u> /s/ GISELE DION </u> Gisele Dion	Director	March 27, 2024
<u> /s/ ROY FREEMAN, M.D. </u> Roy Freeman, M.D.	Director	March 27, 2024
<u> /s/ PAUL GRINT, M.D. </u> Paul Grint, M.D.	Director	March 27, 2024
<u> /s/ DENNIS BERMAN </u> Dennis Berman	Director	March 27, 2024



**Inhibikase
Therapeutics**

Inhibikase Therapeutics, Inc.

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