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PROSPECTUS

Up to 11,627,908 shares of Common Stock underlying the Common Warrants

Up to 4,883,721 shares of Common Stock underlying the Pre-Funded Warrants

Up to 406,977 shares of Common Stock underlying the Placement Agent Warrants

Inhibikase Therapeutics, Inc.

This prospectus relates to the resale from time to time, by the selling stockholders (the "Selling Stockholders") identified in this prospectus under the caption "Selling Stockholders," of (i) up to 11,627,908 shares of common stock, par value $0.001 per share (the "Common Stock"), which the selling stockholders may acquire upon the exercise of outstanding warrants (the "Common Warrants"), (ii) up to 4,883,721 shares of Common Stock, which the Selling Stockholders may acquire upon the exercise of outstanding pre-funded warrants (the "Pre-Funded Warrants"), and (iii) up to 406,977 shares of Common Stock, which the selling stockholders may acquire upon the exercise of outstanding placement agent warrants (the "Placement Agent Warrants", and together with the Common Warrants, and Pre-Funded Warrants, the "Warrants").

We issued the Common Warrants and Pre-Funded Warrants to the Selling Stockholders in private placements concurrent with a registered direct offering of 2,800,789 shares of Common Stock and Pre-Funded Warrants to purchase 3,943,398 shares of Common Stock. We issued the Placement Agent Warrants to Selling Stockholders as designees of H.C. Wainwright & Co., as placement agent fees for serving as the exclusive placement agent in the registered direct offering and concurrent private placements.

The closing of the issuance and sale of these securities was consummated on January 27, 2023.

The selling stockholder of the securities and any of their pledgees, assignees and successors-in-interest may, from time to time, sell any or all of their securities covered hereby on the principal trading market or any other stock exchange, market or trading facility on which the securities are traded or in private transactions. These sales may be at fixed or negotiated prices. See "Plan of Distribution" in this prospectus for more information. We will not receive any proceeds from the resale or other disposition of the Common Stock by the Selling Stockholders. However, we will receive the proceeds of any cash exercise of the Warrants. See "Use of Proceeds" beginning on page 73 and "Plan of Distribution" beginning on page 78 of this prospectus for more information.

Our Common Stock is listed on the Nasdaq Capital Market ("Nasdaq") under the symbol "IKT." On March 30, 2023, the last reported sale price of our Common Stock was $0.68 per share.

We are an "emerging growth company" and a "smaller reporting company," each as defined under the federal securities laws and, as such, have elected to comply with certain reduced reporting requirements for this prospectus and may elect to do so in future filings. See the section titled "Implications of Being an Emerging Growth Company and a Smaller Reporting Company."

Investing in our securities involves a high degree of risk. See "Risk Factors" beginning on page 7 of this prospectus and elsewhere in this prospectus for a discussion of information that should be considered in connection with an investment in our securities.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense. The securities are not being offered in any jurisdiction where the offer is not permitted.

The date of this prospectus is April 4, 2023.

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Prospectus

PROSPECTUS SUMMARY

This summary highlights selected information contained elsewhere in this prospectus and is qualified in its entirety by the more detailed information and financial statements included elsewhere in this prospectus. It does not contain all of the information that maybe important to you and your investment decision. You should carefully read this entire prospectus, including the matters set forth under the sections titled "Risk Factors", "Special Note Regarding Forward-Looking Statements", and "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and related notes. In this prospectus, unless context requires otherwise, references to "we," "us," "our," or "the Company" refer to Inhibikase Therapeutics, Inc. See the section titled "Glossary" starting at page 161 for definitions of key scientific and technical terms used in this prospectus.

Overview

Inhibikase Therapeutics, Inc.

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 IkT-148009, c-Abl inhibitor, targets the treatment of Parkinson's disease inside and outside the brain as well as other diseases that arise from Abelson Tyrosine Kinases. In 2021, we commenced clinical development of IkT-148009, which we believe can modify the course of Parkinson's disease including its manifestation in the gastrointestinal tract, or GI. The FDA review of the Phase 1/1b data and the protocol for the Phase 2a three-month dosing study resulted in the FDA agreeing with the Company's view that it was appropriate for the Phase 2a study to begin, prompting the Company to initiate the Phase 2a study, the 201 trial, at the end of May 2022. In October 2022, an IND to expand use of IkT-148009 into the Parkinson's-related disease Multiple System Atrophy ("MSA") was filed with the FDA. On November 7, 2022, following review of the IND for IkT-148009 as a treatment for MSA, the FDA notified the Company that it was placing theIkT-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 on the MSA program, opening the IND for MSA. Twenty of thirty-five planned sites will be open as of the date of this prospectus, with screening anticipated to start in early 2Q23 and 120 patients planned to be enrolled overall. The 201 in Parkinson's trial will start screening patients for enrollment at 50 mg and 100 mg, with the 200 mg dose added back into the trial following submission of the safety and steady-state pharmacokinetic data of the 200 mg dose that was collected in March 2023. Once this data is submitted, the 200 mg dose will be added to the trial after 15 patients have been randomized to 50 mg, 100 mg or placebo groups. The FDA further requested the measurement of visual acuity and examination of the cornea and lens to complement the analysis of retina, macula and fundus that was already part of the ocular monitoring program in the 201 trial.

Our evaluation of 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 IkT-148009 as a therapy for MSA. These animal studies are now under way and our pursuit of clinical development will depend on a demonstration of therapeutic benefit in at least one animal model to proceed with clinical development. We plan to initiate a Phase 2 safety and tolerability study in MSA patients in up to nineteen sites in the EU, and up to six sites in the U.S. involving 60 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 6-months. If IkT-148009 is not a successful therapy in MSA animal model studies, the Phase 2 clinical study will not proceed. In this circumstance, the regulatory effort for IkT-148009 in the EU would be applied to future studies of Parkinson's Disease efficacy in the EU. The Company plans to pursue orphan drug designation for IkT-148009 to treat MSA with regulators in the U.S. and Europe.

The Company is also developing platform technologies for alternate ways to deliver protein kinase inhibitors in patients. Our first example of this technology is IkT-001Pro, a prodrug of the anticancer agent imatinib mesylate, to treat Stable Phase Chronic Myelogenous Leukemia (SP-CML). Pursuant to its IND which was cleared by the FDA in August 2022, IkT-001Pro is being evaluated in a two-part dose finding/dose equivalence study in up to 59 healthy volunteers (the 501 trial). The study is 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 400 mg imatinib, the standard-of-care dose for SP-CML. As of the date of this prospectus, three of four dose escalation cohorts have completed the trial; it is anticipated that the dose finding/dose equivalence program will be completed by the end of the second quarter of 2023. Only four mild adverse events have been observed, none of clinical significance for IkT-001Pro. IkT-001Pro has high oral bioavailability and a pharmacokinetic profile of delivered imatinib that closely matches the exposure of imatinib delivered as 400 mg imatinib mesylate. Following the 501 study, Inhibikase will confer with the FDA and seek agreement on the requirements for the NDA process following the proposed approval path for IkT-001Pro under the 505(b)(2) approval pathway. The Company plans to simultaneously pursue a superiority study comparing the selected doses of IkT-001Pro to standard-of-care 400 mg imatinib in SP-CML patients using a novel, two-period-wait-list- crossover-switching study.

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 is planned to be completed in 2023.

In our opinion, the multi-decade failures in the treatment of neurodegenerative diseases such as PD result from a lack of understanding of the biochemistry of the disease processes involved. Neurodegeneration is marked by a progressive degeneration and loss of function of neurons which send and receive signals to and from the brain. Historically, the cause of a neurodegenerative disease was thought to be a “plaque” made up of a misfolded and/ or aggregated protein(s). Therapeutic approaches, therefore, sought to remove “plaque” from the brain. A “plaque”-focused treatment strategy has failed to alter the course of Parkinson’s disease in two Phase 2 trials that reported results in 2020 and 2021. We believe we are different. We identified the proteins that become dysfunctional in a disease pathway and sought to understand how a dysfunctional protein causes disease. We believe our approach to PD and other neurological diseases has identified the underlying cause of disease and led to an understanding of how individual proteins are linked together to define the disease process. Using this strategy, we believe we have discovered at least one enzyme that plays a pivotal role in the disease process for PD, the Abelson Tyrosin Kinase c-Abl. We have developed novel protein kinase inhibitors against c-Abl, which we believe can alter the disease course for PD. C-Abl chemically modifies the “plaque” proteins in PD, known as alpha-synuclein. Chemical modification creates what we believe to be the true toxic entity of the disease. Treatment with IkT-148009 may prevent chemical modification and, at least in animal models of progressive disease, leads to near clearance of the toxic form of alpha-synuclein from the affected neurons.

We believe we are one of the pioneers of the application of protein kinase inhibitors to non-oncology indications, including neurodegeneration and infectious diseases, as well as their more traditional role in the treatment of cancer. Prior to becoming a publicly-traded company in 2020, more than 50% of the Company’s total funding had been received from Private, State and Federal granting agencies, including the National Institutes of Health, the Department of Defense and the Michael J. Fox Foundation, with the balance the result of equity sales in the private sector. Private, State and Federal granting agencies use extensive scientific peer review in deciding which projects to fund that could impact human disease. Our ability to advance the Company on the basis of scientific peer review reflects the potential our scientific peers see for the possible success of our therapeutic programs.

Recent Developments

Publication of Studies Describing Potential of IkT-148009

On January 25, 2023, the Company announced the publication of studies describing the potential of IkT-148009 as a disease-modifying therapy for Parkinson’s disease and related disorders. The publication entitled *“The c-Abl*

*inhibitor IkT-148009 suppresses neurodegeneration in mouse models of heritable and sporadic Parkinson's disease"*was published online in the journal Science *Translational Medicine* on January 18, 2023 (DOI: 10.1126/scitranslmed.abp9352).

Nasdaq Listing

As previously disclosed on a Current Reporton Form 8-K filed on July 29, 2022, on July 25, 2022, the Company received a deficiency letter from the Listing Qualifications Department (the "Staff") of The Nasdaq Stock Market LLC ("Nasdaq") informing the Company that its Common Stock was below the minimum $1.00 per share requirement for continued inclusion on The Nasdaq Capital Market pursuant to Nasdaq Listing Rule 5550(a)(2) (the "Minimum Bid Price Requirement") based on the closing bid price of the Common Stock for the 30 consecutive business days prior to the date of the notice from Nasdaq.

On January 24, 2023, the Company received notice from Nasdaq indicating that, while the Company has not regained compliance with the Minimum Bid Price Requirement, Nasdaq has determined that the Company is eligible for an additional 180-day period, or until July 24, 2023, to regain compliance. According to the notice from Nasdaq, the Staff's determination was based on (i) the Company meeting the continued listing requirement for the market value of its publicly held shares and all other Nasdaq initial listing standards, with the exception of the Minimum Bid Price Requirement, and (ii) the Company's written notice to Nasdaq of its intention to cure the deficiency during the second compliance period by effecting a reverse stock split, if necessary. If at any time during this second 180-day compliance period, the closing bid price of the Common Stock is at least $1.00 per share for a minimum of 10 consecutive business days, Nasdaq will provide the Company with written confirmation of compliance. If compliance cannot be demonstrated by July 24, 2023, Nasdaq will provide written notification that the Common Stock will be delisted. At that time, the Company may appeal Nasdaq's determination to a Hearings Panel.

Lifting of the Clinical Hold on IkT-148009 in Parkinson's disease and Multiple Systems Atrophy

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

In January 2023, the FDA lifted its clinical hold on theIkT-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 IkT-148009-201 and various modifications to the Investigator Brochure. The Company intends to restart the 201 trial immediately with two doses (50 mg and 100 mg). The Company further intends to provide FDA safety and pharmacokinetics data for the 200 mg dose from the Company's proposed 7-day MAD study in 6 healthy volunteers aged 45-70 to support adding back the 200 mg dose to the 201 trial. The FDA further requested the measurement of visual acuity and examination of the cornea and lens to complement the analysis of retina, macula and fundus that was already part of the ocular monitoring program in the 201 trial. On March 2, 2023, the FDA lifted the clinical hold on IkT-148009 in MSA allowing the Company to proceed with its plans for a future Phase 2 clinical trial in MSA.

Although the clinical hold on theIkT-148009 program has been lifted, we can provide no assurance that we will not be subject to a clinical hold in the future. 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 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.

Termination of the Equity Distribution Agreement

On May 16, 2022, the Company entered into an Equity Distribution Agreement (the "Equity Distribution 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, in an aggregate offering price of up to $9,801,287 through the Agent. Under the terms of the Equity Distribution 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. No shares of Common Stock were sold pursuant to the Equity Distribution Agreement. Effective January 25, 2023, the Company terminated the Equity Distribution Agreement by providing a notice of termination to the Agent in accordance with the terms of the Equity Distribution Agreement.

Company Information

We were incorporated in Delaware in 2010 as a successor to a Georgia limited liability company and commenced operations in September 2008. Our principal executive offices are located at 3350 Riverwood Parkway SE, Suite 1900, Atlanta, Georgia, 30339. We also maintain offices at 1 Cranberry Hill, Ste 200, Lexington, MA, 02421. Our telephone numbers are (678) 392-3419 and (617) 936-0184. Our website address is www.inhibikase.com. Information contained on our website is not incorporated by reference into this prospectus, and it should not be considered to be part of this prospectus.

Implications of Being an Emerging Growth Company and a Smaller Reporting Company

We qualify as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, as amended, or the JOBS Act. As an "emerging growth company," we may take advantage of specified reduced disclosure and other requirements that are otherwise applicable generally to public companies. These provisions include, but are not limited to:

- requiring only two years of audited financial statements in addition to any required unaudited interim financial statements with correspondingly reduced "Management's discussion and analysis of financial condition and results of operations" in our Securities Act of 1933, as amended, or the Securities Act, filings;
- reduced disclosure about our executive compensation arrangements;
- No non-binding advisory votes on executive compensation or golden parachute arrangements; and
- exemption from compliance with the auditor attestation requirement in the assessment of our internal control over financial reporting pursuant to Section 404(b) of the Sarbanes Oxley Act of 2002, or SOX.

We may take advantage of these exemptions for up to five years or such earlier time that we are no longer an "emerging growth company." 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 December 2020 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 Securities and Exchange Commission, or the SEC.

We are also a "smaller reporting company" as defined in the Securities Exchange Act of 1934, as amended, or the 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.

We may choose to take advantage of some, but not all, of these exemptions. We have taken advantage of reduced reporting requirements in this prospectus. Accordingly, the information contained herein may be different from the information you receive from other public companies in which you hold stock. In addition, the JOBS Act provides that an emerging growth company may take advantage of an extended transition period for complying with new or revised accounting standards, delaying the adoption of these accounting standards until they would apply to private companies. We have elected to avail ourselves of the extended transition period for complying with new or revised financial accounting standards. As a result of the accounting standards election, we will not be subject to the same implementation timing for new or revised accounting standards as other public companies that are not emerging growth companies which may make comparison of our financials to those of other public companies more difficult.

THE OFFERING

Common stock offered by us	16,918,606 shares of Common Stock issuable upon exercise of the Warrants.
Use of proceeds	We will not receive any proceeds from the Common Stock offered by the Selling Stockholders under this prospectus. However, we will receive the proceeds of any cash exercise of the Warrants. We intend to use the net proceeds from any cash exercise of the Warrants for working capital and general corporate purposes. See "Use of Proceeds."
Market for Common Stock	Our Common Stock is listed on the Nasdaq Capital Market under the symbol "IKT." On March 30, 2023, the last reported sale price of our Common Stock was $0.68 per share.
Risk Factors	See "Risk Factors" beginning on page 7 and the other information included in this prospectus for a discussion of factors you should carefully consider before investing in our securities.

The number of shares of our Common Stock to be outstanding after this offering is based on the 28,977,238 shares of our Common Stock outstanding as of March 14, 2023, and excludes the following:

- 4,826,208 shares of Common Stock issuable upon exercise of options outstanding as of March 14, 2023, with a weighted average exercise price of $2.07 per share;
- 4,555,911 shares of Common Stock issuable upon exercise of warrants outstanding (excluding the Warrants) as of March 14, 2023, with a weighted average exercise price of $1.79 per share; and
- 7,058,812 shares of Common Stock reserved for future grant or issuance as of March 14, 2023, under our equity incentive plan.

Unless otherwise indicated, this prospectus reflects and assumes no exercise of outstanding options and warrants.

RISK FACTORS

Investing in our Common Stock involves a high degree of risk. You should carefully consider the risks described below, as well as the other information in this prospectus, 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 prospectus, before deciding whether to invest in our Common Stock. 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 Common Stock 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;
- While the FDA lifted the clinical holds with respect to theIkT-148009 programs relating to Parkinson's disease and MSA, we may be subject to further clinical holds by the FDA in the future;
- We have received deficiency notices from the Nasdaq Capital Market, which may require a reverse stock split of our Common Stock. If we are unable to cure these deficiencies and meet the Nasdaq continued listing requirements, we could be delisted from the Nasdaq Capital Market, which would negatively impact the trading of our Common Stock;
- If we are unable to successfully raise additional capital, our future clinical trials and product development could be limited and our long-term viability may be threatened;
- Drug development is a highly uncertain undertaking and involves a substantial degree of risk. We have never generated any revenue from product sales, we may never generate any revenue from product sales, and we may fail to generate further revenue from grants or contracts or to be profitable;
- The war between Russia and Ukraine 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 theCOVID-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 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;

- 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; and
- An insider controls 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.

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 prospectus, 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 prospectus 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.

While the FDA lifted the clinical holds with respect to the 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 IND application forIkT-148009 for the treatment of MSA and had issued a clinical hold on the IkT-148009 201 program in PD and the use of IkT-148009 in MSA.

In January 2023, the FDA lifted its clinical hold on theIkT-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 IkT-148009-201 and various modifications to the Investigator Brochure. The Company intends to restart the 201 trial immediately with two doses (50 mg and 100 mg). The Company further intends to provide FDA safety and pharmacokinetics data for the 200 mg doses from the Company's proposed 7-day MAD study in 6 healthy volunteers aged 45-70 to support adding back the

200 mg dose. The FDA further requested the measurement of visual acuity and examination of the cornea and lens to complement the analysis of retina, macula and fundus that was already part of the ocular monitoring program in the 201 trial. On March 8, 2023, the FDA lifted the clinical hold on IkT-148009 in MSA allowing the Company to proceed with its plans for a future Phase 2 clinical trial in MSA.

Although the clinical hold on the 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 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.

We received deficiency notices from the Nasdaq Capital Market. If we are unable to cure these deficiencies, which may require a reverse stock split of our Common Stock, and meet the Nasdaq continued listing requirements, we could be delisted from the Nasdaq Capital Market, which would negatively impact the trading of our Common Stock.

On July 25, 2022, we received a notice from the Listing Qualifications Staff of Nasdaq indicating that, based upon the closing bid price of the Company's common stock, for the 30 consecutive business days prior to the notice, the Company no longer met the requirement to maintain a minimum closing bid price of $1.00 per share, as set forth in Nasdaq Listing Rule 5550(a)(2) (the "Minimum Bid Price Requirement"). The Company was originally granted 180 calendar days, or until January 23, 2023, to regain compliance with the Minimum Bid Price Requirement. On January 24, 2023, Nasdaq notified the Company that it had been granted an additional 180-calendar day compliance period, or until July 24, 2023, to regain compliance with the Minimum Bid Price Requirement. In connection with the grant of such additional compliance period, the Company provided notice to Nasdaq that it intended to cure the bid price deficiency by effecting a reverse stock split, if necessary, prior to the end of the compliance period.

In order to regain compliance with the Minimum Bid Price Requirement, we plan to implement a reverse stock split of our common stock unless the Company otherwise is able to regain compliance with the Minimum Bid Price Requirement. Although we expect that the reverse stock split will result in a sustained increase in the market price of our common stock, the reverse stock split may not result in a permanent increase in the market price of our common stock, which is dependent on many factors, including general economic, market and industry conditions and other factors detailed from time to time in the reports we file with the SEC. As a result, there can be no assurance that the market price per share of our common stock after the reverse stock split will remain above the Minimum Bid Price Requirement. It is not uncommon for the market price of a company's common stock to decline in the period following a reverse stock split. If the market price of our common stock declines following the effectuation of the proposed reverse stock split, the percentage decline may be greater than would occur in the absence of a reverse stock split. In any event, other factors unrelated to the number of shares of our common stock outstanding, such as negative financial or operational results, could adversely affect the market price of our common stock and jeopardize our ability to meet or maintain compliance with Nasdaq's Minimum Bid Price Requirement. If the market price per share of our common stock following the proposed reverse stock split decreases below Nasdaq's Minimum Bid Price Requirement, we could again be subject to further delisting procedures by Nasdaq.

In addition, to maintain continued listing on Nasdaq, we must satisfy minimum financial and other continued listing requirements and standards, including those regarding director independence and independent committee requirements, minimum stockholders' equity, and certain corporate governance requirements. If we are unable to satisfy these requirements or standards, we could be subject to delisting, which would have a negative effect on the price of our common stock and would impair your ability to sell or purchase our common

stock when you wish to do so. Although we expect that the proposed reverse stock split will result in a sustained increase in the market price of our common stock, we can provide no assurance that the proposed reverse stock split would enable us to regain or remain in compliance, stabilize the market price or improve the liquidity of our common stock, prevent our common stock from dropping below the Nasdaq Minimum Bid Price Requirement in the future, or prevent future non-compliance with the continued listing requirements.

If our common stock is delisted by Nasdaq, our common stock may be eligible for quotation on an over-the-counter quotation system or on the pink sheets. Upon any such delisting, our common stock would become subject to the regulations of the SEC relating to the market for penny stocks. A penny stock is any equity security not traded on a national securities exchange that has a market price of less than $5.00 per share. The regulations applicable to penny stocks may severely affect the market liquidity for our common stock and could limit the ability of stockholders to sell securities in the secondary market. In such a case, an investor may find it more difficult to dispose of or obtain accurate quotations as to the market value of our common stock, and there can be no assurance that our common stock will be eligible for trading or quotation on any alternative exchanges or markets.

Delisting from Nasdaq could adversely affect our ability to raise additional financing through public or private sales of equity securities, would significantly affect the ability of investors to trade our securities and would negatively affect the value and liquidity of our common stock. Delisting could also have other negative results, including the potential loss of confidence by employees, the loss of institutional investor interest and fewer business development opportunities.

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 and in January 2023 we completed afollow-on public offering and concurrent private placements (the “January 2023 Offering”). 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.

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.

The war between Russia and Ukraine could materially adversely affect our business, results of operations, and financial condition.

In February 2022, Russian military forces invaded Ukraine, and although the length, impact, and outcome of the ongoing war in Ukraine is highly unpredictable, this war has 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 situation in Ukraine and assessing its impact on our business.

We have no way to predict the progress or outcome of the war in Ukraine or its impacts in Ukraine, Russia, or Belarus as the war, and any resulting government reactions, are rapidly developing and beyond our control. The extent and duration of the war, 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 prospectus.

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

The continuing impact that the COVID-19 virus will have on our operations, including duration, severity and scope, remains highly uncertain and cannot be fully predicted at this time. Such impact is a function of the scope of any new virus mutations and outbreaks, the nature of government public health guidelines and the public's adherence to those guidelines, the rate of individuals becoming fully vaccinated, the public's adherence to guidelines to receive booster shots, the success of business and economic recovery as the pandemic recedes, unemployment levels, the extent to which new shutdowns may be needed and the impact of any further government economic relief on the U.S. economy. The coronavirus may continue to spread globally, adversely affecting global economies and financial markets, has and may materially and adversely impact our operations including, without limitation, the functioning of our laboratories, the availability of supplies including reagents,

demand for our services and travel, customer demand and employee health and availability. 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 theCOVID-19 virus could continue to adversely impact our results of operations, cash flows and financial condition in the future. At this time, the Biden Administration does not plan to renew the COVID-19 national and public health emergencies when they expire on May 11, 2023, which has been extended every 90 days since they were established in 2020. This decision, therefore, appears to represent a de-escalation in the way the government treats the pandemic, as well as a perception that most people have either been vaccinated or have recovered from a COVID-19 infection (or both), Despite this anticipated change in policy, COVID-19 is still with us and as the virus continues to reproduce and mutate, the Administration's policy may need be adjusted. In any event, 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 $18,054,155 and $14,786,063 for the years ended December 31, 2022 and 2021, respectively. As of December 31, 2022, we had an accumulated deficit of $47,871,842.

We have invested significant financial resources in research and development activities, including for our product candidates and our RAMP™ 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 ofIkT-148009;
- continue the development of our RAMP™ 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 theCOVID-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 and our January 2023 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 2a clinical trial of 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 $7,188,553 and marketable securities of $15,861,620 as of December 31, 2022. After taking into consideration the January 2023 Offering, the Company estimates that its working capital is sufficient to fund its normal operations through December 2024. 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, 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 IkT-148009 and IkT-001Pro. Our product candidates, including 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 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.

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 Phase II clinical trials for 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 is in the early stages of development, has not undergone clinical trials except in the case of our Phase I and Phase II clinical trials and our two-part dose finding/dose equivalence study for IkT-001Pro, and 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 preclinical studies of our product candidates are not necessarily predictive of the results of later preclinical studies and any current and future clinical trials of our product candidates. If we cannot show positive results or replicate any positive results from our earlier preclinical studies of our product candidates in our later preclinical studies and current and future clinical trials, we may be unable to successfully develop, obtain regulatory approval for and commercialize our product candidates.

Any positive results from 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 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, IkT-148009, and other product candidates and commencing our Phase I and Phase II clinical trials forIkT-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. Except for the commencement of our Phase I, Ib and IIa clinical trial for IkT-148009 for PD and our bioequivalence study ofIkT-001Pro, none of our product candidates have advanced into late-stage development or a pivotal clinical trial and it may be years before any such trial 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 subpopulations 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. 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 timeframe 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 diseases 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, such as the clinical hold the FDA placed and then lifted on our IKT 148009 program in PD. 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 theCOVID-19 pandemic;
- 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 products have 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;
- 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 reactions 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 Squib, Roche Holdings AG, Prothena Corporation plc, Sanofi S.A., Takeda Pharmaceutical Co. Ltd., UCB, S.A., Denali Therapeutics, Prevail Therapeutics, Sun SPARC, FirstBio and AbbVie. 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 asco-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 licenses 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 innovator sues 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 our share price.

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 forIkT-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. If the FDA does not allow us to pursue 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 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 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 would 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 timeframes. 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 sourced 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 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 prodrug 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 rand 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 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) remains pending and is currently awaiting examination by the United States Patent and Trademark Office. We have also applied to register our INHIBIKASE trademark in several foreign countries, including Australia, Canada, European Union, Japan, Switzerland and the United Kingdom, and those applications are currently pending and are not yet registered. We have not applied to register any of our other trademarks in any foreign country and do not know if they are available for use and registration outside of the United States. In sum, other than the three U.S. federal registrations noted above, we have not yet registered any of our trademarks or trade names in any of our 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 March 14, 2023, we had six 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 and March 1, 2023, 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.

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 restricted stock and/or stock option grants that vest over time. 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.

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 carryforwards and certain other tax attributes may be limited.

As of December 31, 2022, we had federal net operating loss carryforwards of approximately $23.3 million, which will begin to expire in varying amounts beginning in 2030. These net operating loss carryforwards 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, 2022, the Company capitalized $9.8 million and $2 million of domestic and foreign R&D expenses, respectively.

To the extent that we continue to generate taxable losses, unused losses will carryforward to offset future taxable income, if any. We may be limited in the portion of net operating loss carryforwards 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 carryforwards 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 carryforwards may also be subject to limitation under state laws. Further, our ability to utilize net operating loss carryforwards 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

We do not know whether an active, liquid and orderly market will develop or be sustained for our common stock or what the market price of our common stock will be, and, as a result, it may be difficult for you to sell your shares of our common stock.

Before our initial public offering in December 2020, there was no public trading market for our common stock. If a market for our common stock does not develop or be sustained, it may be difficult for you to sell your shares of common stock at an attractive price or at all. We cannot predict the prices at which our common stock will trade. It is possible that in one or more future periods our results of operations and progression of our product candidates may not meet the expectations of public market analysts and investors, and, as a result of these and other factors, the price of our common stock may fall.

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.

The number of shares of our Common Stock outstanding after this offering is based on 28,977,238 shares of our Common Stock outstanding as of March 14, 2023. 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 27% 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 14, 2023, Dr. Werner alone beneficially owned shares representing approximately 19.1% 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 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 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. In this prospectus, 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. 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. For example, we expect that the rules and regulations applicable to us as a public company may make it more difficult and more expensive for us to maintain director and officer liability insurance, which could make it more difficult for us to attract and retain qualified members of our board of directors. We are currently evaluating these rules and regulations and cannot predict or estimate the amount of additional costs we may incur or the timing of such costs. These rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

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 timeframe or at all, that our internal control over financial reporting is effective as required by Section 404 of 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 issues 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 downgrade 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 carrybacks 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. In addition, on March 27, 2020, then President Trump signed into law the "Coronavirus Aid, Relief, and Economic Security Act" or the CARES Act, which, among other things, suspends the 80% limitation on the deduction for net operating losses arising in taxable years beginning before January 1, 2021, permits a five-year carryback of net operating losses arising in taxable years beginning after December 31, 2017 and before January 1, 2021, and generally modifies the limitation on the deduction for net interest expense to 50% of adjusted taxable income for taxable years beginning in 2019 and later. The Tax 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, 2022, the Company capitalized $9.8 million and $2 million of domestic and foreign R&D expenses, respectively.

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.

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 sanctions 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.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements concerning our business, operations and financial performance and condition, as well as our plans, objectives and expectations for our business operations and financial performance and condition. Any statements contained herein that are not statements of historical facts may be deemed to be forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as "can", "may", "could", "should", "assume", "forecasts", "believe", "designed to", "will", "expect", "plan", "anticipate", "estimate", "potential", "position", "predicts", "strategy", "guidance", "intend", "budget", "seek", "project" or "continue", or the negative thereof or other comparable terminology regarding beliefs, plans, expectations or intentions regarding the future. You should read statements that contain these words carefully because they:

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

We believe it is important to communicate our expectations. However, forward-looking statements are based on our current expectations, assumptions, estimates and projections about our business and our industry and are subject to known and unknown risks, uncertainties and other factors. Accordingly, our actual results and the timing of certain events may differ materially from those expressed or implied in such forward-looking statements due to a variety of factors and risks, including, but not limited to, those set forth under "Risk Factors" in this prospectus, and the following factors and risks:

- We are a clinical-stage drug development company with limited resources, a limited operating history and have no products approved for commercial sale, which may make it difficult to evaluate our current business and predict our future success and viability;
- While the FDA lifted the clinical holds with respect to theIkT-148009 programs relating to Parkinson's disease and MSA, we may be subject to further clinical holds by the FDA in the future;
- We have received deficiency notices from the Nasdaq Capital Market, which may require a reverse stock split of our Common Stock. If we are unable to cure these deficiencies and meet the Nasdaq continued listing requirements, we could be delisted from the Nasdaq Capital Market, which would negatively impact the trading of our Common Stock;
- If we are unable to successfully raise additional capital, our future clinical trials and product development could be limited and our long-term viability may be threatened;
- Drug development is a highly uncertain undertaking and involves a substantial degree of risk. We have never generated any revenue from product sales, we may never generate any revenue from product sales, and we may fail to generate further revenue from grants or contracts or to be profitable;
- The war between Russia and Ukraine 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 theCOVID-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 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;
- 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; and
- An insider controls 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.

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

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

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

MARKET, INDUSTRY AND OTHER DATA

This prospectus contains estimates, projections and other information concerning our industry, our business and the markets for our product candidates. We obtained the industry, market and similar data set forth in this prospectus from our own internal estimates and research and from academic and industry research, publications, surveys and studies conducted by third parties, including governmental agencies. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances that are assumed in this information. While we believe that the data we use from third parties is reliable, we have not separately verified these data. Although we are responsible for all of the disclosure contained in this prospectus and we believe the information from third-party sources included in this prospectus is reliable, such information is inherently imprecise. The industry in which we operate is subject to a high degree of uncertainty and risk due to a variety of factors, including those described in the section titled "Risk Factors." These and other factors could cause results to differ materially from those expressed in the estimates made by the independent parties and by us. Further, while we believe our internal research is reliable, such research has not been verified by any third-party. You are cautioned not to give undue weight to any such information, projections and estimates.

In some cases, we do not expressly refer to the sources from which data is derived. In that regard, when we refer to one or more sources of this type of data in any paragraph, you should assume that other data of this type appearing in the same paragraph is derived from the same sources, unless otherwise expressly stated or the context otherwise requires.

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

1. S. Brahmachari, et al., "Activation of tyrosine kinasec-Abl contributes to α-synuclein-induced neurodegeneration." *J. Clin. Invest*, 126: 2970-88 (2016).
2. X. Mao, et al., "Pathological α-synuclein transmission initiated by binding lymphocyte-activation gene 3." *Science,* 353 (2016).
3. The Michael J. Fox Foundation website (www.michaeljfox.org).
4. The Cure Parkinson's Trust website (www.cureparkinsons.org.uk).
5. Parkinson's Disease Foundation (www.pdf.org), Decisions Resources 2016 Parkinson's Report.
6. Jones J.D., et al., "Health comorbidities and cognition in 1948 patients with idiopathic Parkinson's Disease."*Parkinsonism and Related Disorders*, 18:1073-1078 (2012).
7. Wright Willis, et al., "Geographic and ethnic variation in Parkinson Disease: a population-based study of US Medicare beneficiaries." *Neuroepidemiology*, 34:143-151 (2012).
8. de Rijk, et al., "Prevalence of parkinsonism and Parkinson's Disease in Europe: the EUROPARKINSON Collaborative Study. European Community Concerted Action on the Epidemiology of Parkinson's Disease." *J Neurol Neurosurg Psychiatry*, 62:10-5 (1997).
9. Ying Zhao, et al., "Progression of Parkinson's Disease as Evaluated by Hoehn and Yahr Stage Transition Times."*Movement Disorders* 25:710-716 (2010).

USE OF PROCEEDS

We will not receive any proceeds from the sale of the shares of Common Stock by the Selling Stockholders. However, we will receive proceeds from the exercise of the Warrants by the Selling Stockholders to the extent they are exercised for cash. We estimate that the maximum proceeds that we may receive from the exercise of the Warrants, assuming all the Warrants are exercised at their average exercise price of $0.54, will be $9,158,920. We do not know, however, whether any of the Warrants will be exercised or, if any of the Warrants are exercised, when they will be exercised. It is possible that the Warrants will expire and never be exercised. There are circumstances under which the Warrants may be exercised on a cashless basis. In these circumstances, even if the Warrants are exercised, we may not receive any proceeds, or the proceeds that we do receive may be significantly less than what we might expect. We intend to use the aggregate net proceeds from the exercise of the Warrants for general corporate purposes, including working capital. The actual allocation of proceeds realized from the exercise of these Warrants will depend upon the amount and timing of such exercises, our operating revenues and cash position at such time and our working capital requirements. The Selling Stockholders will pay any expenses incurred by the Selling Stockholders for brokerage, accounting, tax or legal services or any other expenses incurred by the Selling Stockholders in disposing of its shares of Common Stock. We will bear all other costs, fees and expenses incurred in effecting the registration of the shares covered by this prospectus, including, without limitation, all registration fees and fees and expenses of our counsel and our accountants.

MARKET PRICE OF OUR COMMON STOCK AND RELATED STOCKHOLDER MATTERS

Market Information

Our Common Stock is listed on the Nasdaq Capital Market under the symbol "IKT." A description of our Common Stock is set forth under the heading "Description of Capital Stock" beginning on page 153 of this prospectus.

The last reported sale price for our Common Stock on March 30, 2023 was $0.68 per share.

Holders

As of March 14, 2023, we had 14 record holders of our Common Stock and no preferred stock issued and outstanding. The number of record holders was determined from the records of our transfer agent and does not include beneficial owners of Common Stock whose shares are held in the names of various security brokers, dealers, and registered clearing agencies. The transfer agent of our Common Stock is American Stock Transfer & Trust Company. The transfer agent and registrar's address is 6201 15th Ave, Brooklyn, NY 11219.

Dividend Policy

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.

PRIVATE PLACEMENT OF SHARES OF COMMON STOCK AND WARRANTS

In a private placement in January 2023 (the "Registered Direct Private Placement"), we sold to a single institutional investor unregistered common warrants (the "Private Common Warrants") to purchase up to 6,744,187 shares of our Common Stock. Each Private Common Warrant has an exercise price of $0.75 per share, is exercisable upon issuance and will expire on January 27, 2028. The Private Common Warrants were offered pursuant to the exemptions provided in Section 4(a)(2) under the Securities Act 1933, as amended (the "Securities Act") and Regulation D promulgated thereunder and, along with the shares of our Common Stock issuable upon the exercise of the Private Common Warrants (the "Private Common Warrant Shares"), have not been registered under the Securities Act, or applicable state securities laws. Accordingly, the Private Common Warrants and the Private Common Warrant Shares underlying the Private Common Warrants may not be offered or sold in the U.S. except pursuant to an effective registration statement or an applicable exemption from the registration requirements of the Securities Act and such applicable state securities laws.

In a private placement in January 2023 (the "PIPE Private Placement"), we sold to the same institutional investor (i) unregistered pre-funded warrants (the "PIPE Pre-funded Warrants") to purchase up to an aggregate of 4,883,721 shares of our Common Stock; and (ii) unregistered common warrants (the "PIPE Common Warrants") to purchase up to an aggregate of 4,883,721 shares of our Common Stock, representing 100% of the shares underlying the PIPE Pre-funded Warrants purchased in the offering.

The PIPE Pre-funded Warrants are exercisable upon issuance and will expire when exercised in full. The purchase price of each PIPE Pre-funded Warrant was equal to the price per share at which the shares of Common Stock were sold in a concurrent registered direct offering of (i) 2,800,789 shares of our Common Stock, $0.001 par value per share, and (ii) pre-funded warrants to purchase up to an aggregate of 3,943,398 shares of our Common Stock, minus $0.0001, the exercise price per share of each PIPE Pre-funded Warrant. Each PIPE Common Warrant has an exercise price of $0.75 per share, is exercisable upon issuance and will expire on January 27, 2028.

The PIPE Pre-funded Warrants and the PIPE Common Warrants were offered pursuant to the exemptions provided in Section 4(a)(2) under the Securities Act and Regulation D promulgated thereunder and, along with the PIPE Pre-funded Warrant Shares and the PIPE Common Warrant Shares, have not been registered under the Securities Act, or applicable state securities laws. Accordingly, the PIPE Pre-funded Warrants, the PIPE Pre-funded Warrant Shares, the PIPE Common Warrants and the PIPE Common Warrant Shares may not be offered or sold in the U.S. except pursuant to an effective registration statement or an applicable exemption from the registration requirements of the Securities Act and such applicable state securities laws.

We paid H.C. Wainwright & Co., LLC ("Wainwright") a cash fee equal to 7.0% of the gross proceeds received from the investor who purchased securities in the registered direct offering and the concurrent private placements and issued to designees of Wainwright warrants ("Placement Agent Warrants") to purchase up to 406,977 shares of Common Stock (which represents 3.5% of the aggregate number of shares of Common Stock and Pre-Funded Warrants sold in the registered direct offering and the concurrent private placements) on substantially the same terms as the Private Common Warrants except with an exercise price of $1.075 (or 125% of the offering price per share) and an expiration date of January 25, 2028, which is the five-year anniversary of the commencement of the sales pursuant to the registered direct offering. We paid Wainwright in connection with the registered direct offering and the concurrent private placements $70,000 for non-accountable expenses and $15,950 for clearing fees. The total offering expenses of the registered direct offering payable by us, excluding the placement agent's fees and expenses, was approximately $300,000.

SELLING STOCKHOLDERS

The Common Stock being offered by the Selling Stockholders are those previously issued to the Selling Stockholders, and those issuable to the Selling Stockholders, upon exercise of the warrants. For additional information regarding the issuances of those shares of common stock and warrants, see "Private Placement of Shares of Common Stock and Warrants" above. We are registering the shares of Common Stock in order to permit the Selling Stockholders to offer the shares for resale from time to time. Except for the ownership of the shares of Common Stock and the warrants, the Selling Stockholders have not had any material relationship with us within the past three years.

The table below lists the Selling Stockholders and other information regarding the beneficial ownership of the shares of Common Stock by each of the Selling Stockholders. The second column lists the number of shares of Common Stock beneficially owned by each Selling Stockholders, based on its ownership of the shares of Common Stock and warrants, as of March 29, 2023, assuming exercise of the warrants held by the Selling Stockholders on that date, without regard to any limitations on exercises. The third and fourth columns assume the sale of all of the shares offered by the Selling Stockholders pursuant to this prospectus.

The third column lists the shares of Common Stock being offered by this prospectus by the Selling Stockholders.

In accordance with the terms of a registration rights agreement with Armistice Capital Master Fund Ltd. (the "Master Fund"), this prospectus generally covers the resale of the maximum number of shares of Common Stock issuable upon exercise of the Warrants. This prospectus also covers the resale of the Placement Agent Warrants issued to the designees of H.C. Wainwright & Co., who served as exclusive placement agent in the registered direct offering and concurrent private placements.

Under the terms of the Warrants, a Selling Stockholder may not exercise the warrants to the extent such exercise would cause such Selling Stockholder, together with its affiliates and attribution parties, to beneficially own a number of shares of Common Stock which would exceed 4.99% or 9.99%, as applicable, of our then outstanding Common Stock following such exercise, excluding for purposes of such determination shares of Common Stock issuable upon exercise of such Warrants which have not been exercised. The number of shares in the table below does not reflect this limitation. The Selling Stockholder may sell all, some or none of their shares in this offering. See "Plan of Distribution."

Name of Selling Stockholders	Shares Owned prior to Offering	Shares Offered by this Prospectus	Shares Owned after Offering	Percentage of Shares Beneficially Owned after Offering (1)
Armistice Capital Master Fund Ltd. (2)	20,387,585(3)	16,511,629(4)	3,875,956	13.4%
Michael Vasinkevich (5)	260,974	260,974	0	0%
Sean Hagerty (5)	77,326	77,326	0	0%
Noam Rubinstein (5)	50,872	50,872	0	0%
Craig Schwabe (5)	13,735	13,735	0	0%
Charles Worthman (5)	4,070	4,070	0	0%

(1) Percentages are based on 28,977,238 shares of Common Stock outstanding as of March 14, 2023.

(2) The securities are directly held as of March 14, 2023, by the Master Fund, a Cayman Islands exempted company, and may be deemed to be indirectly beneficially owned by Armistice Capital, LLC ("Armistice"), as the investment manager of the Master Fund; and (ii) Steven Boyd, as the Managing Member of Armistice. Armistice and Steven Boyd disclaim beneficial ownership of the reported securities except to the extent of their respective pecuniary interest therein. The address of Armistice Capital Master Fund Ltd. is c/o Armistice Capital, LLC, 510 Madison Avenue, 7th Floor, New York, NY 10022. Under the terms of the

Warrants, a Selling Stockholder may not exercise the warrants to the extent such exercise would cause such Selling Stockholder, together with its affiliates and attribution parties, to beneficially own a number of shares of Common Stock which would exceed 4.99% or 9.99%, as applicable, of our then outstanding Common Stock following such exercise, excluding for purposes of such determination shares of Common Stock issuable upon exercise of such Warrants which have not been exercised. The beneficial ownership of the Master Fund reported in this table does not reflect this limitation.

(3) Consists of (i) 2,960,956 shares of Common Stock, (ii) Common Warrants to purchase up to 11,627,908 shares of Common Stock, and (iii) Pre-Funded Warrants to purchase up to 5,798,721 shares of Common Stock.

(4) Consists of (i) Common Stock underlying Common Warrants to purchase up to 11,627,908 shares of Common Stock and (ii) Common Stock underlying Pre-Funded Warrants to purchase up to 4,883,721 shares of Common Stock.

(5) The Selling Stockholder is affiliated with H.C. Wainwright & Co., LLC, a registered broker-dealer, and has a registered address of c/o H.C. Wainwright & Co., LLC, 430 Park Ave, 3rd Floor, New York, NY 10022, and has sole voting and dispositive power over the securities held. The number of shares being registered hereby for resale consist of shares of Common Stock issuable upon exercise of Placement Agent Warrants, which were received as compensation in connection with our January 2023 private placements. The Selling Stockholder purchased the placement agent warrants in the ordinary course of business and, at the time of purchase of the securities that are registered for resale, the Selling Stockholder had no agreements or understanding, directly or indirectly, with any person to distribute such securities.

PLAN OF DISTRIBUTION

Each Selling Stockholder of the securities and any of their pledgees, assignees and successors-in-interest may, from time to time, sell any or all of their securities covered hereby on the principal trading market or any other stock exchange, market or trading facility on which the securities are traded or in private transactions. These sales may be at fixed or negotiated prices. A Selling Stockholder may use any one or more of the following methods when selling securities:

- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which the broker-dealer will attempt to sell the securities as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- settlement of short sales;
- in transactions through broker-dealers that agree with the Selling Stockholders to sell a specified number of such securities at a stipulated price per security;
- through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise;
- a combination of any such methods of sale; or
- any other method permitted pursuant to applicable law.

The Selling Stockholders may also sell securities under Rule 144 or any other exemption from registration under the Securities Act, if available, rather than under this prospectus.

Broker-dealers engaged by the Selling Stockholders may arrange for other brokers-dealers to participate in sales. Broker-dealers may receive commissions or discounts from the Selling Stockholders (or, if any broker-dealer acts as agent for the purchaser of securities, from the purchaser) in amounts to be negotiated, but, except as set forth in a supplement to this Prospectus, in the case of an agency transaction not in excess of a customary brokerage commission in compliance with FINRA Rule 2121; and in the case of a principal transaction a markup or markdown in compliance with FINRA Rule 2121.

In connection with the sale of the securities or interests therein, the Selling Stockholders may enter into hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short sales of the securities in the course of hedging the positions they assume. The Selling Stockholders may also sell securities short and deliver these securities to close out their short positions, or loan or pledge the securities to broker-dealers that in turn may sell these securities. The Selling Stockholders may also enter into option or other transactions with broker-dealers or other financial institutions or create one or more derivative securities which require the delivery to such broker-dealer or other financial institution of securities offered by this prospectus, which securities such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction).

The Selling Stockholders and any broker-dealers or agents that are involved in selling the securities may be deemed to be “underwriters” within the meaning of the Securities Act in connection with such sales. In such event, any commissions received by such broker-dealers or agents and any profit on the resale of the securities purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act. Each Selling Stockholder has informed the Company that it does not have any written or oral agreement or understanding, directly or indirectly, with any person to distribute the securities.

The Company is required to pay certain fees and expenses incurred by the Company incident to the registration of the securities. The Company has agreed to indemnify the Selling Stockholders against certain losses, claims, damages and liabilities, including liabilities under the Securities Act.

We agreed to keep this prospectus effective until the earlier of (i) the date on which the securities may be resold by the Selling Stockholders without registration and without regard to any volume or manner-of-sale limitations by reason of Rule 144, without the requirement for the Company to be in compliance with the current public information under Rule 144 under the Securities Act or any other rule of similar effect or (ii) all of the securities have been sold pursuant to this prospectus or Rule 144 under the Securities Act or any other rule of similar effect. The resale securities will be sold only through registered or licensed brokers or dealers if required under applicable state securities laws. In addition, in certain states, the resale securities covered hereby may not be sold unless they have been registered or qualified for sale in the applicable state or an exemption from the registration or qualification requirement is available and is complied with.

Under applicable rules and regulations under the Exchange Act, any person engaged in the distribution of the resale securities may not simultaneously engage in market making activities with respect to the common stock for the applicable restricted period, as defined in Regulation M, prior to the commencement of the distribution. In addition, the Selling Stockholders will be subject to applicable provisions of the Exchange Act and the rules and regulations thereunder, including Regulation M, which may limit the timing of purchases and sales of the common stock by the Selling Stockholders or any other person. We will make copies of this prospectus available to the Selling Stockholders and have informed them of the need to deliver a copy of this prospectus to each purchaser at or prior to the time of the sale (including by compliance with Rule 172 under the Securities Act).

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 prospectus. This discussion and analysis and other parts of this prospectus 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 prospectus. 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 IkT-148009, c-Abl inhibitor, targets the treatment of Parkinson's disease inside and outside the brain as well as other diseases that arise from Abelson Tyrosine Kinases. In 2021, we commenced clinical development of IkT-148009, which we believe can modify the course of Parkinson's disease including its manifestation in the gastrointestinal tract, or GI. The FDA review of the Phase 1/1b data and the protocol for the Phase 2a three-month dosing study resulted in the FDA agreeing with the Company's view that it was appropriate for the Phase 2a study to begin, prompting the Company to initiate the Phase 2a study, the 201 trial, at the end of May 2022. In October 2022, an IND to expand use of IkT-148009 into the Parkinson's-related disease Multiple System Atrophy ("MSA") was filed with the FDA. On November 7, 2022, following review of the IND for IkT-148009 as a treatment for MSA, the FDA notified the Company that it was placing theIkT-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 on the MSA program, opening the IND for MSA. Twenty of thirty-five planned sites will be open as of the date of this prospectus, with screening anticipated to start in early 2Q23 and 120 patients planned to be enrolled overall. The 201 in Parkinson's trial will start screening patients for enrollment at 50 mg and 100 mg, with the 200 mg dose added back into the trial following submission of the safety and steady-state pharmacokinetic data of the 200 mg dose that was collected in March 2023. Once this data is submitted, the 200 mg dose will be added to the trial after 15 patients have been randomized to 50 mg, 100 mg or placebo groups. The FDA further requested the measurement of visual acuity and examination of the cornea and lens to complement the analysis of retina, macula and fundus that was already part of the ocular monitoring program in the 201 trial.

Our evaluation of 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 IkT-148009 as a therapy for MSA. These animal studies are now under way and our pursuit of clinical development will depend on a demonstration of therapeutic benefit in at least one animal model to proceed with clinical development. We plan to initiate a Phase 2 safety and tolerability study in MSA patients in up to nineteen sites in the EU, and up to six sites in the U.S. involving 60 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 6-months. If IkT-148009 is not a successful therapy in MSA animal model studies, the Phase 2 clinical study will not proceed. In this circumstance, the regulatory effort for IkT-148009 in the EU would be applied to future studies of Parkinson's Disease efficacy in the EU. The Company plans to pursue orphan drug designation for IkT-148009 to treat MSA with regulators in the U.S. and Europe.

The Company is also developing platform technologies for alternate ways to deliver protein kinase inhibitors in patients. Our first example of this technology is IkT-001Pro, a prodrug of the anticancer agent imatinib mesylate, to treat Stable Phase Chronic Myelogenous Leukemia (SP-CML). Pursuant to its IND which was cleared by the FDA in August 2022, IkT-001Pro is being evaluated in a two-part dose finding/dose equivalence study in up to 59 healthy volunteers (the 501 trial). The study is 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 400 mg imatinib, the standard-of-care dose for SP-CML. As of the date of this prospectus, three of four dose escalation cohorts have completed the trial; it is anticipated that the dose finding/dose equivalence program will be completed by the end of the second quarter of 2023. Only four mild adverse events have been observed, none of clinical significance for IkT-001Pro. IkT-001Pro has high oral bioavailability and a pharmacokinetic profile of delivered imatinib that closely matches the exposure of imatinib delivered as 400 mg imatinib mesylate. Following the 501 study, Inhibikase will confer with the FDA and seek agreement on the requirements for the NDA process following the proposed approval path for IkT-001Pro under the 505(b)(2) approval pathway. The Company plans to simultaneously pursue a superiority study comparing the selected doses of IkT-001Pro to standard-of-care 400 mg imatinib in SP-CML patients using a novel, two-period-wait-list- crossover-switching study.

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 is planned to be completed in 2023.

In our opinion, the multi-decade failures in the treatment of neurodegenerative diseases such as PD result from a lack of understanding of the biochemistry of the disease processes involved. Neurodegeneration is marked by a progressive degeneration and loss of function of neurons which send and receive signals to and from the brain. Historically, the cause of a neurodegenerative disease was thought to be a “plaque” made up of a misfolded and/or aggregated protein(s). Therapeutic approaches, therefore, sought to remove “plaque” from the brain. A “plaque”-focused treatment strategy has failed to alter the course of Parkinson’s disease in two Phase 2 trials that reported results in 2020 and 2021. We believe we are different. We identified the proteins that become dysfunctional in a disease pathway and sought to understand how a dysfunctional protein causes disease. We believe our approach to PD and other neurological diseases has identified the underlying cause of disease and led to an understanding of how individual proteins are linked together to define the disease process. Using this strategy, we believe we have discovered at least one enzyme that plays a pivotal role in the disease process for PD, the Abelson Tyrosin Kinase c-Abl. We have developed novel protein kinase inhibitors against c-Abl, which we believe can alter the disease course for PD. C-Abl chemically modifies the “plaque” proteins in PD, known as alpha-synuclein. Chemical modification creates what we believe to be the true toxic entity of the disease. Treatment with IkT-148009 may prevent chemical modification and, at least in animal models of progressive disease, leads to near clearance of the toxic form of alpha-synuclein from the affected neurons.

We believe we are one of the pioneers of the application of protein kinase inhibitors to non-oncology indications, including neurodegeneration and infectious diseases, as well as their more traditional role in the treatment of cancer. Prior to becoming a publicly-traded company in 2020, more than 50% of the Company’s total funding had been received from Private, State and Federal granting agencies, including the National Institutes of Health, the Department of Defense and the Michael J. Fox Foundation, with the balance the result of equity sales in the private sector. Private, State and Federal granting agencies use extensive scientific peer review in deciding which projects to fund that could impact human disease. Our ability to advance the Company on the basis of scientific peer review reflects the potential our scientific peers see for the possible success of our therapeutic programs.

Impact of the ongoing military conflict between Russia and Ukraine

In late February 2022, Russia invaded Ukraine, significantly amplifying already existing geopolitical tensions among Russia and other countries in the region and in the west, including the U.S. Russia’s invasion, the

responses of countries and political bodies to Russia's actions, the larger overarching tensions, and Ukraine's military response and the potential for wider conflict have resulted in financial market volatility and capital markets disruption and inflation, potentially increasing in magnitude, and could have severe adverse effects on regional and global economic markets and international relations. The extent and duration of the military action, sanctions and resulting market disruptions are impossible to predict, but could be substantial.

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

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

Components of Operating Results

Operating Expenses

Research and Development

Research and development activities account for a significant portion of our operating expenses. Research and development expenses accounted for 66% and 64% of our operating expenses for the years ended December 31, 2022 and 2021, 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 withIND-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 identifyin-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 theCOVID-19 pandemic which has had an adverse impact on our business, including our preclinical studies and clinical trials;
- our ability to commercialize products, if and when approved, whether alone or in collaboration with others; and
- the continued acceptable safety profiles of the product candidates following approval.

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

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,		
	2022	2021	Change
PD	$ 9,645,457	$ 9,530,534	$ 114,923
MSA	468,016	265,567	202,449
CML	1,460,754	754,348	706,406
Other research and development expenses	460,758	808,655	(347,897)
Total research and development expenses	12,034,985	11,359,104	675,881

Selling, General and Administrative

Selling, general and administrative expenses include personnel related expenses, such as salaries, benefits, travel andnon-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 compared to when we were a private company, including expenses related to compliance with the rules and regulations of the SEC and those of any national securities exchange on which our securities are traded, additional insurance expenses, investor relations activities and other administrative and professional services. We also expect to 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, 2022 and 2021

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

	Year Ended December 31,		Change	
	2022	2021	($)	(%)
Grant revenue	$ 123,440	$ 3,100,605	$ (2,977,165)	(96.0)
Research and development	(12,034,985)	(11,359,104)	(675,881)	6.0
Selling, general and administrative	(6,217,063)	(6,507,641)	290,578	(4.5)
Loss from operations	(18,128,608)	(14,766,140)	(3,362,468)	(22.8)
Interest income/(expense), net	74,453	(19,923)	94,376	(473.7)
Net loss	$ (18,054,155)	$ (14,786,063)	$ (3,268,092)	(22.1)

Grant Revenue

Grant revenue for the year ended December 31, 2022 decreased by $2,977,165 or 96% to $123,440 from $3,100,605 in the prior year. The decrease was driven by decreased grant research activity during 2022 compared

to 2021. During 2022, the Company's focus was shifted toward advancing its Phase I and II clinical trials which were not submitted for grant revenue. The Company utilized its working capital and personnel resources in 2022 to carry on its Phase I and II clinical trial in addition to its grant research activity.

Research and Development

Research and development expenses increased by $675,881 or 6% to $12,034,985 from $11,359,104 in the prior year. The increase was driven by a $0.7 million increase due to ongoing non-grant related research and development activities mostly related to the Phase 2a '201' clinical trial.

Selling, General and Administrative

Selling, general and administrative expenses decreased by $290,578 or 4.5% to $6,217,063 from $6,507,641 in the prior year. The decrease was primarily the result of decreased warrant expense of $0.7 million, and stock based compensation of $0.5 million, which were offset by an increase in legal fees of $0.4 million, regulatory and compliance fees of $0.2 million, and a net increase of $0.3 million for other normal operating expenses.

Interest Income

Interest income increased by $74,453 from $nil in the prior comparable period. The increase was driven by interest earned on U.S. Treasuries and money market instruments commencing in July 2022. In the prior comparable period, the Company held cash in non-interest bearing accounts.

Interest Expense

Interest expense decreased by $19,923 or 100% to $nil from $19,923 in the prior year. The decrease was driven by the extinguishment of all outstanding notes payable by January 3, 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, 2022, we generated aggregate cash proceeds of approximately $23.6 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 $8.7 million respectively, in net proceeds from its 2020 IPO, its June 2021 Offering, and its January 2023 Offering, respectively.

On May 16, 2022, the Company entered into an Equity Distribution Agreement (the "Equity Distribution 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, in an aggregate offering price of up to $9,801,287 through the Agent. Under the terms of the Equity Distribution 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. No shares of Common Stock were sold pursuant to the Equity Distribution Agreement. Effective January 25, 2023, the Company terminated the Equity Distribution Agreement by providing a notice of termination to the Agent in accordance with the terms of the Equity Distribution Agreement.

At December 31, 2022, the Company had working capital of $20,675,677, an accumulated deficit of $47,871,842, cash and cash equivalents of $7,188,553 and marketable securities of $15,861,620 and accounts payable and accrued expenses of $3,549,609.

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 $47,871,842 at December 31, 2022. We expect to incur substantial additional losses in the future as we conduct and expand our research and development activities.

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

The Company had working capital of $20,675,677 at December 31, 2022. 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 a future capital raise, 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 believe that our existing cash resources as of December 31, 2022 and our January 2023 offering will enable us to fund our operating requirements into the fourth quarter of 2024. However, we have based these estimates on assumptions that may prove to be wrong, and we could deplete our working capital sooner than planned.

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

- the timing and progress of preclinical and clinical development activities;
- the number and scope of preclinical and clinical programs we decide to pursue;
- possible delays or interruptions to preclinical studies, clinical trials, our receipt of services from our third-party service providers on whom we rely, or our supply chain due to the COVID-19 pandemic;
- the progress of the development efforts of third parties with whom we have entered into license and collaboration agreements;
- our ability to maintain our current research and development programs and to establish new research and development, license or collaboration arrangements;
- our ability and success in securing manufacturing relationships with third parties or, in the future, in establishing and operating a manufacturing facility;
- the costs involved in prosecuting, defending and enforcing patent claims and other intellectual property claims;
- the cost and timing of regulatory approvals;
- our efforts to enhance operational, financial and information management systems and hire additional personnel, including personnel to support development of our product candidates; and
- the costs and ongoing investments to in-license and/or acquire additional technologies.

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

Cash Flows

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

	Year Ended December 31,	
	2022	2021
Net cash used in operating activities	$ (17,351,103)	$ (14,297,051)
Net cash used in investing activities	$ (16,005,708)	$ —
Net cash (used in)/provided by financing activities	$ (204,769)	$ 41,093,671
Net (decrease)/increase in cash and cash equivalents	$ (33,561,580)	$ 26,796,620

Net Cash Flows Used in Operating Activities

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 of depreciation and lease expense of 34,920, 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.

Net cash flows used in operating activities for the year ended December 31, 2021 totaled $14,297,051, and consisted primarily of a net loss of $14,786,063 adjusted for non-cash stock compensation of $1,531,876, non-cash warrant expense of $688,784, non-cash consulting fees of $60,391, non-cash PPP loan forgiveness of $27,550, decrease in accounts receivable of $110,141, decrease in prepaid expenses and other assets of $1,447,888, decrease in accounts payable of $630,902, decrease in deferred revenue of $2,325,741, increase in prepaid research and development of $667,356 and an increase in accrued expenses and other current liabilities of $2,082,827.

Cash Used in Investing Activities

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 and $20,725,462 was used for the purchase of marketable securities investments and $4,963,009 was provided by maturity of marketable securities.

Cash (Used in)/Provided by Financing Activities

Net cash used by 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.

Net cash flows provided by financing activities for the year ended December 31, 2021 totaled $41,093,671, which consisted of $41,135,357 in proceeds from issuance of common stock in connection with our June 2021 Offering offset by $42,534 in debt payments.

We raised $14.6 million, $41.1 million and $8.7 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

In June 2018, the Company entered into a one-year, noncancelable operating lease for space in Boston, Massachusetts. The total lease obligation was $54,000, payable in 12 equal monthly installments commencing August 1, 2018. On April 18, 2022, the Company entered into an operating lease agreement through 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 $444,366, consisting of minimum annual rental obligations of $33,469 for fiscal year 2022, $145,836 for fiscal year 2023, $150,095 for fiscal year 2024 and $114,966 for fiscal year 2025.

Critical Accounting Policies and Significant Judgments and Estimates

This discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States, or 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 prospectus, 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 Black-Scholes-Merton option pricing model requires management to determine the fair market value of the common

stock at the date of the award. Prior to our December 2020 initial public offering, the fair market value of the common stock was determined utilizing the risk adjusted net present value, or rNPV, option-pricing model as performed by an independent third-party consultant. Since December 22, 2020, the fair market value of the common stock is determined by reference to the closing price of our common stock on the Nasdaq Capital Market on the grant date of the option.

For options or warrants granted to non-employee consultants prior to January 1, 2020, the fair value of these options was remeasured using the Black-Scholes-Merton option-pricing model reflecting the same assumptions as applied to employee options in each of the reported periods, other than the expected life, which is assumed to be the remaining contractual life of the option.

Prior to January 1, 2020, we accounted for stock-based compensation arrangements withnon-employee consultants using a fair value approach. The estimated fair value of unvested options granted to non-employee consultants was remeasured at each reporting date through the date of final vesting. As a result, the non-cash charge to operations for non-employee options with vesting conditions was affected in each reporting period by changes in the estimated fair value of our common stock. We adjust for actual forfeitures as they occur.

On January 1, 2020, the Company adopted ASU No. 2018-07, *Compensation – Stock Compensation (Topic 718): Improvements to Non-employee Share-Based Payment Accounting* ("ASU 2018-07"), which expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from non-employee consultants. The estimated fair value of unvested options granted tonon-employee consultants is no longer remeasured at each reporting date through the date of final vesting. The adoption of this ASU did not have a material impact on the Company's financial statements.

As there had been no public market for our common stock prior to our December 2020 initial public offering, the estimated fair value of our common stock had been determined by an independent third-party consultant using an rNPV process and approved by our board of directors. The factors utilized by such independent third-party consultant included, but were not limited to: our results of operations, financial position and capital resources; current business conditions and projections; the lack of marketability of our common stock; the hiring of key personnel and the experience of management; the risk inherent in the development of our products and our stage of development and material risks related to its business; the fact that the option grants involve illiquid securities in a private company; and the likelihood of achieving a liquidity event, such as an initial public offering or sale, in light of prevailing market conditions.

All of our common stock valuations prior to our December 2020 initial public offering have been prepared by an independent third-party consultant using the rNPV method.

Following the closing of our December 2020 initial public offering, our board of directors will determine the fair market value of our stock-based awards based on the closing price of our common stock as reported on the date of grant on the Nasdaq Capital Market exchange on which our common stock is traded.

The intrinsic value of all in the money outstanding options as of December 31, 2022 was approximately $0.3 million, based on the closing price of our common stock of $0.50 per share at December 31, 2022, 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.

BUSINESS

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 IkT-148009, c-Abl inhibitor, targets the treatment of Parkinson's disease inside and outside the brain as well as other diseases that arise from Abelson Tyrosine Kinases. In 2021, we commenced clinical development of IkT-148009, which we believe can modify the course of Parkinson's disease including its manifestation in the gastrointestinal tract, or GI. The FDA review of the Phase 1/1b data and the protocol for the Phase 2a three-month dosing study resulted in the FDA agreeing with the Company's view that it was appropriate for the Phase 2a study to begin, prompting the Company to initiate the Phase 2a study, the 201 trial, at the end of May 2022. In October 2022, an IND to expand use of IkT-148009 into the Parkinson's-related disease Multiple System Atrophy, or MSA, was filed with the FDA. On November 7, 2022, following review of the IND for IkT-148009 as a treatment for MSA, the FDA notified the Company that it was placing the IkT-148009 programs for Parkinson's disease and MSA on clinical hold. The FDA lifted the full clinical hold in January 2023 for the Parkinson's programs and in March 2023 on the MSA program, opening the IND for MSA. Twenty of thirty-five planned sites will be open as of the date of this prospectus, with screening anticipated to start in early 2Q23 and 120 patients planned to be enrolled overall. The 201 in Parkinson's trial will start screening patients for enrollment at 50 mg and 100 mg, with the 200 mg dose added back into the trial following submission of the safety and steady-state pharmacokinetic data of the 200 mg dose that was collected in March 2023. Once this data is submitted, the 200 mg dose will be added to the trial after 15 patients have been randomized to 50 mg, 100 mg or placebo groups. The FDA further requested the measurement of visual acuity and examination of the cornea and lens to complement the analysis of retina, macula and fundus that was already part of the ocular monitoring program in the 201 trial.

Our evaluation of 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 IkT-148009 as a therapy for MSA. These animal studies are now under way and our pursuit of clinical development will depend on a demonstration of therapeutic benefit in at least one animal model to proceed with clinical development. We plan to initiate a Phase 2 safety and tolerability study in MSA patients in up to nineteen sites in the EU, and up to six sites in the U.S. involving 60 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 6-months. If IkT-148009 is not a successful therapy in MSA animal model studies, the Phase 2 clinical study will not proceed. In this circumstance, the regulatory effort for IkT-148009 in the EU would be applied to future studies of Parkinson's Disease efficacy in the EU. The Company plans to pursue orphan drug designation for IkT-148009 to treat MSA with regulators in the U.S. and Europe.

The Company is also developing platform technologies for alternate ways to deliver protein kinase inhibitors in patients. Our first example of this technology is IkT-001Pro, a prodrug of the anticancer agent imatinib mesylate, to treat Stable Phase Chronic Myelogenous Leukemia (SP-CML). Pursuant to its IND which was cleared by the FDA in August 2022, IkT-001Pro is being evaluated in a two-part dose finding/dose equivalence study in up to 59 healthy volunteers (the 501 trial). The study is 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 400 mg imatinib, the standard-of-care dose for SP-CML. As of the date of this prospectus, three of four dose escalation cohorts have completed the trial; it is anticipated that the dose finding/dose equivalence program will be completed by the end of the second quarter of 2023. Only four mild adverse events have been observed, none of clinical significance for IkT-001Pro. IkT-001Pro has high oral bioavailability and a pharmacokinetic profile of delivered imatinib that closely matches the exposure of imatinib delivered as 400 mg imatinib mesylate. Following the 501 study, Inhibikase will confer with the FDA and seek agreement on the requirements for the NDA process

following the proposed approval path for IkT-001Pro under the 505(b)(2) approval pathway. The Company plans to simultaneously pursue a superiority study comparing the selected doses of IkT-001Pro to standard-of-care 400 mg imatinib in SP-CML patients using a novel, two-period-wait-list- crossover-switching study.

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 is planned to be completed in 2023.

In our opinion, the multi-decade failures in the treatment of neurodegenerative diseases such as PD result from a lack of understanding of the biochemistry of the disease processes involved. Neurodegeneration is marked by a progressive degeneration and loss of function of neurons which send and receive signals to and from the brain. Historically, the cause of a neurodegenerative disease was thought to be a “plaque” made up of a misfolded and/ or aggregated protein(s). Therapeutic approaches, therefore, sought to remove “plaque” from the brain. A “plaque”-focused treatment strategy has failed to alter the course of Parkinson’s disease in two Phase 2 trials that reported results in 2020 and 2021. We believe we are different. We identified the proteins that become dysfunctional in a disease pathway and sought to understand how a dysfunctional protein causes disease. We believe our approach to PD and other neurological diseases has identified the underlying cause of disease and led to an understanding of how individual proteins are linked together to define the disease process. Using this strategy, we believe we have discovered at least one enzyme that plays a pivotal role in the disease process for PD, the Abelson Tyrosin Kinase c-Abl. We have developed novel protein kinase inhibitors against c-Abl, which we believe can alter the disease course for PD. C-Abl chemically modifies the “plaque” proteins in PD, known as alpha-synuclein. Chemical modification creates what we believe to be the true toxic entity of the disease. Treatment with IkT-148009 may prevent chemical modification and, at least in animal models of progressive disease, leads to near clearance of the toxic form of alpha-synuclein from the affected neurons.

We believe we are one of the pioneers of the application of protein kinase inhibitors to non-oncology indications, including neurodegeneration and infectious diseases, as well as their more traditional role in the treatment of cancer. Prior to becoming a publicly-traded company in 2020, more than 50% of the Company’s total funding had been received from Private, State and Federal granting agencies, including the National Institutes of Health, the Department of Defense and the Michael J. Fox Foundation, with the balance the result of equity sales in the private sector. Private, State and Federal granting agencies use extensive scientific peer review in deciding which projects to fund that could impact human disease. Our ability to advance the Company on the basis of scientific peer review reflects the potential our scientific peers see for the possible success of our therapeutic programs.

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 Progressive, Multifocal Leukoencephalopathy, Multiple System Atrophy and Chronic Myelogenous Leukemia.

We currently have worldwide commercialization rights to all of our development programs and IP protection until 2033 or later.

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 nearly 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 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 IkT-148009 and imatinib, we believe we can take advantage of the linear correlation between side effects and oral dose because 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 IkT-148009, IkT-148009 appears to have a more favorable safety and tolerability profile than the template used to design it.

Our Portfolio

IkT-148009: 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 1,200,000 persons in the United States, with 60,000 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. Almost all patients with Parkinson's disease will eventually need to take medication to help with their symptoms. Worldwide, there could be as many as 10,000,000 cases of PD. By 2025, PD drug sales are expected to double; sales estimates by 2025 are expected to crest $6.0 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, psychosis and dementia. The future market for treatment is believed to be robust, with the compound annual growth rates of 2.7% and 1.8% for patients that are diagnosed and not diagnosed respectively. We expect those growth rates to continue for the foreseeable future. In the U.S. market, patients currently expend $15,000 to $25,000 per year to treat the symptoms of PD, creating a multi-billion-dollar opportunity for disease-modification of this devastating disease. Moreover, since the same product 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

1 J.M. Savitt, V.L. Dawson, T. M. Dawson, Diagnosis and treatment of Parkinson disease: molecules to medicine.*J Clin Invest.* 116, 1744-1754 (2006).
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).
4 M. Goedert, M.G. Spillantini, K. Del Tredici, H. Braak, 100 years of Lewy pathology.*Nat Rev Neurol.* 9, 13-24 (2013).
5 V.M. Lee, J. Q. Trojanowski, Mechanisms of Parkinson's Disease linked to pathological alpha-synuclein: new targets for drug discovery*Neuron*. 52, 33-38 (2006).

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.

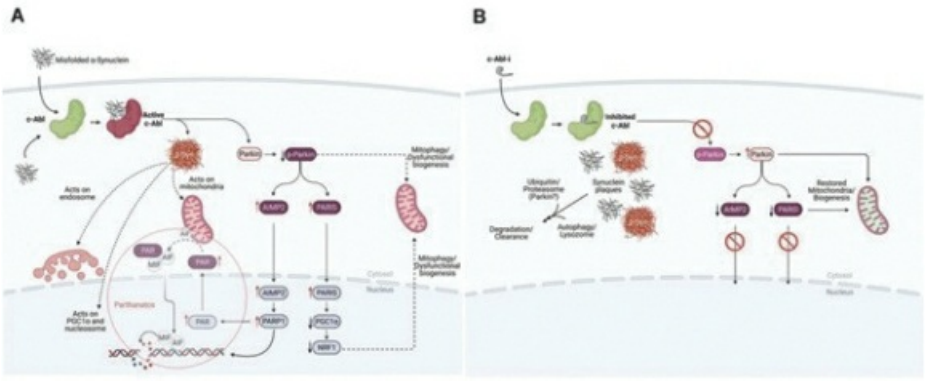


Fig. 1: The Biochemistry of Parkinson's Disease Initiation and Progression and How to Disrupt It

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-1α 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.

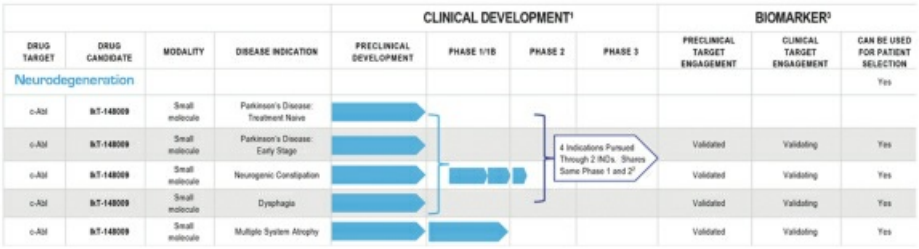
B. The consequences of c-Abl inhibitor treatment on the process of neurodegenerative disease. Inhibition of c-Abl precludes c-Abl activation, blocking the build-up of toxic parkin substrates PARIS and AIMP2 and terminating downstream events. This alsore-establishes normal mitochondrial quality control 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.

[6] A.H.V. Schapira, C.W. Olanow, J. T. Greenamyre, E. Bezard, Slowing of neurodegeneration in Parkinson's Disease and Huntington's disease: future therapeutic perspectives. *Lancet* 384, 545-555 (2014).

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.

IkT-148009 for neurodegenerative disease

Table 1



1) 'Clinical Development' progress bars represent the current state of the indicated programs. Blue arrows represent completed or in progress studies; white arrows represent planned approaches for future clinical studies.

(2) Four indications will be pursued for IkT-148009 in PD, which will be pursued through two INDs, one focused on treatment in the brain in treatment naïve or early-stage patients and the second focused on GI complications. MSA is a Parkinson's-like disease to enter clinical development at Phase 2 sharing the Phase 1 data for 148009 with PD. We will move MSA forward in clinic trials only if ongoing animal model studies yield positive results.

(3) For biomarker status, 'Validated' refers to proof of target engagement in the target tissue which has been performed using rodent tissues and fluids. We are currently developing methods for using clinical samples for validating our ability to confirm target engagement in patients. 'Validating' in this context indicates ongoing efforts to prove target engagement using proprietary sources and methods under development from human tissues and fluids. Target engagement measures if and to what extent a compound occupies its target. 'Can be used for patient selection' refers to our ability to use one or more markers we are currently 'Validating' to screen patients for the presence of that marker as a means of defining the patients most likely to benefit from the proposed treatment.

IkT-148009 is a small molecule, brain penetrant c-Abl inhibitor selective for the non-receptor Abelson tyrosine kinases that we are using in clinical trials to treat two groups of PD patients and two additional groups to evaluate GI complications that arise early in the disease course in PD patients. We delineate the GI complications from PD because we will evaluate the GI complications using unique measurements and endpoints that are distinct from PD itself. Thus, we believe we will have four opportunities to succeed with IkT-148009, lowering the risk of failure during the development program. A fifth program for IkT-148009 involves the orphan disease Multiple System Atrophy, which we discuss further below. We believe we have further lowered the risks associated with development of IkT-148009 because we believe key aspects of the underlying pharmacology of IkT-148009 have been shown to be superior to approved drugs in this class. The five indications to which IkT-148009 are planned to be applied are listed in Table 1.

Validated animal models recreate the rate of progression and severity of the human disease

To establish whether IkT-148009 could impact the disease course in PD and related disorders, it was necessary to recreate the human disease in animals for both the location in the body where the disease occurs and for the timeframe of disease progression relative to lifespan. In patients, PD often takes 25 years to lead to death, approximately 1/3 of the average human lifespan in the United States. One-third of the lifespan of a mouse is one year. Thus, to create a true mimic of the human disease, we introduced dysfunctional synuclein aggregates into the mouse brain at the nigrostriatal region near the brainstem, or in the GI tract, and then let the disease slowly-progress. The outcomes of these studies have recently been published.

Efficacy of IkT-148009 in validated, humanized mouse models of PD and related disorders

1. Functional Reversal in the Brain.

About 10% of human PD arises from a genetic defect that leads to inherited disease. One of these inherited defects is theAlanine-to-Threonine mutation at position 53 (A53T) in alpha-synuclein. A53T can be introduced into mouse brain using an adeno-associated vector (AAV vector) that is injected using MRI guidance to place the expression vector for A53T into the nigrostriatal region of mouse brain, the same region of the brain where PD occurs in human patients. Disease in this model develops over a 6-month period to degenerate 50% of dopamine-secreting (DA) neurons, mimicking the timeframe of 50% neurodegeneration in this part of the brain of PD patients. We introduce A53T in just one hemisphere of the mouse brain, so we can use the other brain hemisphere as an internal control. Mice with 50% neurodegeneration in just one hemisphere lose the ability to walk in straight lines, so we measure functional loss and recovery by counting circles traversed by the mice in a fixed period of time.

Six weeks after introduction of A53T, 1x/day dosing ofIkT-148009 was initiated. Functional readout was performed with the amphetamine-rotation test at 6 months of age. Dosing with IkT-148009 resulted in nearly complete restoration of normal function in this test, indicating thatIkT-148009 reversed functional loss in the brain.

Functional reversal is accompanied by halting neurodegeneration and rescue of affected neurons in response to treatment. That we have achieved this outcome can be appreciated from counting the number of neurons in the affected region of the brain using two different staining procedures as well as by measuring the density of neural fibers in the affected region of the brain.[7] The neurons were counted using two different markers of dopaminergic neurons: Tyrosine Hydroxylase (TH) or Nissl. A) staining of dopaminergic neurons in the substantia nigra pars compacta and B) quantitation of neural counts. While IkT-148009 did not have any effect on the number of neurons in control animals lacking A53T, induction of A53T resulted in a75%-80% reduction of dopaminergic neurons 6 months following induction.[7] By contrast, induction of A53T for 5 weeks, followed by initiation ofIkT-148009 treatment by daily oral gavage preserved most dopaminergic neurons (> 80%).[7]

To demonstrate target engagement in the brain following oral, 1x/day administration, the ability ofIkT-148009 to suppress activation of c-Abl can be measured by quantifying the suppression of the active form of c-Abl, which is autophosphorylated at Tyr245. In the presence of 50 mg/kg/day IkT-148009, the ratio of the active:inactive form of c-Abl in the brain returns to levels below baseline in these animals.[7] In the presence of the efflux transporter inhibitor, slightly better inhibition of c-Abl activation is observed.

2. Functional preservation in an acute neurotoxicity model in the brain.

This pre-clinical model uses a chemical neurotoxin, MPTP (1-methyl-4-phenyl-1,2,3,6- tetrahydropyridine), to stimulate c-Abl activation in the absence or presence of IkT-148009.[7] In this model, IkT-148009 substantially protects neurons from degradation as we have recently published.8IkT-148009 treatment in this model blocked nearly all of the neurons in the substantia nigra region of the brain from degradation induced by MPTP, the region of the brain normally affected by PD.

[7] Karuppagounder et al, The c-Abl inhibitor IkT-148009 suppresses neurodegeneration in mouse models of heritable and sporadic Parkinson's disease. Sci Transl. Med (2023); 15: eabp9352.

The degree of neuroprotection arising from IkT-148009 in this acute model is also reflected in the functional behavior of these animals7 In forelimb and grip strength, mice treated with IkT-148009 are nearly identical to control mice that have not been treated with the acute neurotoxin MPTP. These animals also have nearly normal descent times in the 'pole test', a test in which the mice are placed at the top of a two-meter pole and have to navigate their way vertically down the pole.[7]

3. Functional Reversal in the GI Tract

GI dysfunction is among the most prevalent early signs of PD, usually involving irreversible constipation, difficulty emptying stomach contents (known as gastroparesis) and difficulty swallowing (known as dysphagia). To evaluate the ability of IkT-148009 to induce functional reversal in the GI tract, a transgenic mouse was created to express A53T specifically in the GI tract. Animals expressing A53T in the GI tract display a significant slowing in the time it takes for food to be processed from mouth to anus, known as the Whole Gut Transit Time, or WGTT. A53T mice display a nearly 3-fold slowing in WGTT relative to regular mice 3 months after A53T is expressed in the adult mouse (Fig. 2). While normal mice have a WGTT of just 165 minutes, this lengthens to nearly 500 minutes 3 months after A53T is introduced (Fig. 2). Mice treated with just 50 mg/kg/day beginning two months after A53T was introduced, on the other hand, have an average WGTT of just 219 min. If it weren't for the 6 outlier measurements (see cluster plot with blue shading to the right), the average for drug treated mice would be closer to 170 min, a nearly completely normal transit time.

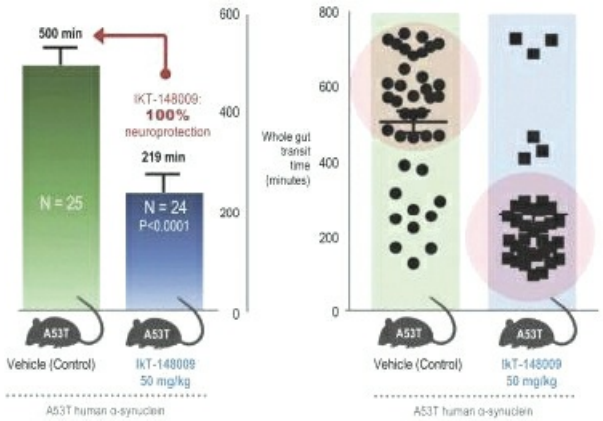


Fig. 2: The Whole Gut Transit Time (WGTT) measured in A53T and wild type human alpha-synuclein transgenic mice in the presence or absence of IkT-148009. The WGTT was measured after 3 months at either 50 or 150 mg/kg/day in mice expressing A53T-alpha-synuclein (only 50 mg/kg/day is shown, 150 mg/kg/day had similar results with an average of 254 min instead of 219 min). The control mice were a dosing solution, or vehicle, without the drug. The control allowed comparison of drug treated mice to mice that express the normal human alpha-synuclein as the only source of alpha-synuclein in their bodies. For each treatment group, the results were statistically significant relative to the no drug vehicle only treated controls with a $P < 0.0001$ in a Student's T-test.

When we evaluate the distribution of toxic alpha-synuclein in the gut, which we track with an antibody against pY39, therapeutic treatment with IkT-148009 results in near clearance of pathological alpha-synuclein, evidenced by the loss of punctate green staining in the images at both 50 and 150 mg/kg treatment (Fig. 3). Thus, functional reversal in the gut is accompanied by clearance of toxic alpha-synuclein as a consequence of IkT-148009 treatment.

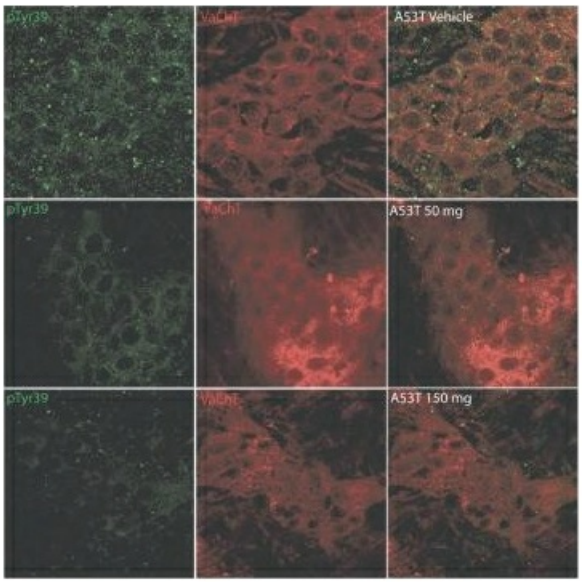


Fig. 3: Effect of IkT-148009 on the presence of pathological pY39 in the adult myenteric plexus of the PDA53T-a-syn mouse model. Fixed longitudinal muscle containing myenteric plexus (LM-MP) tissue from the A53T-a-syn transgenic mice from the three cohorts Vehicle, or the drug IkT-148009 at two different concentrations, 50 mg/Kg and 150 mg/Kg were immunostained with antibodies against pY39 (Rabbit Polyclonal; Green) and VaCht (Goat polyclonal; Red) and with appropriate secondary antibodies. The tissues were then mounted with Prolong Anti-fade and imaged under oil with 40X magnification with an Olympus FV3000rs confocal microscope. The VaCht labels all adult myenteric neurons that express the neurotransmitter and their populations account for almost 70% of adult myenteric neurons. Using the VaCht immunostaining to focus on the myenteric ganglia, we imaged the z-plane that focuses on the myenteric ganglia in the LM-MP tissues and used that plane to observe the presence of pY39 within the myenteric ganglia. Our representative images here show that the expectedly punctate immunostained pY39 protein is abundantly present in and around the neurons of the myenteric ganglia of the Vehicle-dosed A53T mice. However, both the low (50 mg/Kg) and high (150 mg/ Kg) dose of the drug IkT-148009 nearly clears the presence of this pathological protein within the myenteric ganglia and their individual neurons.

We believe that these results in preclinical models establish that reversal of functional loss occurs in the gut just as it has been established in the brain. Functional recovery occurs relatively quickly in the gut, in less than four weeks of daily dosing, although we have not withdrawn drug after functional reversal to determine if treatment with IkT-148009 is curative. However, it is unknown whether these effects will be seen in humans following treatment with IkT-148009.

Toxicology of IkT-148009 in rat and monkey

We have completed 14-day, 3-month and 6-month toxicology studies in rats and 14-day, 3-months and 9-months toxicology studies in monkey. These studies reveal that IkT-148009 has less toxicological impact in these animals for these durations relative to the template molecule imatinib. In long-term toxicology in rat, IkT-148009 had a No Adverse Event Level, or NOAEL, of 15 mg/kg/day as compared to 5 mg/kg/day for imatinib. Similarly, the NOAEL for monkey at 9 months was 75 mg/kg/day for IkT-148009 as compared to 15 mg/kg/day for the

template drug imatinib. The only unexpected observation was the emergence of minimal to mild pathology in the eyes of rats that was not observed in the 9-month study in monkeys. Beginning at 13 weeks, a progressive increase in the frequency of changes to the structures of the eye was observed in rat. These changes included minimal to mild retinal degeneration, partial retinal detachment and evidence of choroid neovascularization, indicating that a monitoring program should be deployed in clinical studies to determine if these changes in the eye may occur in humans. Despite these observations in the eyes of rats, we observed a reduction in the overall toxicology profile of IkT-148009 as the dosing duration increased, suggesting that as the dosing duration is lengthened, there is an adaptation that occurs in different organ systems in response to drug treatment.

Clinical Development Strategy for IkT-148009

Demographics and Adverse Events Observed in Clinical Studies to Date

IkT-148009 has been administered to older and elderly healthy adults in Single and Multiple Ascending Dose studies in humans (SAD and MAD, respectively) with up to 7-day dosing. IkT-148009 has also been administered in Parkinson's patients with mild to moderate disease who remained on symptomatic therapies and received IkT-148009 for up to 7-days. The tables below summarize the demographics of the healthy subjects evaluated in the SAD and MAD studies.

Table 2: Demographics of the Phase 1 Single and Multiple Dose Escalation Study with IkT-148009 in Older and Elderly Healthy Subjects and in Parkinson's patients

Category	Demographic	Healthy Subjects Value (% of Total N=88)	Parkinson Patient Value (% of total, N=25)
Gender	Female	34 (38.6)	9 (36)
	Male	54 (61.4)	15 (60)
Age	Average (SD)	57.9 (5.72)	61.9
	Median	58.0	63
	Range	45, 69	48, 71
Ethnicity	Hispanic or Latino	13 (14.8)	4 (16)
	Not Hispanic or Latino	75 (85.2)	20 (80)
Race	Black or African American	54 (61.4)	3 (12)
	White	33 (37.5)	20 (80)
	Other	1 (1.1)	0 (0)
Adverse events		6, none clinically significant, only 3 possibly drug related	12, none clinically significant, only 4 possibly drug related

72 patients were evaluated in the SAD phase from 12.5 to 325 mg (8 patients/cohort, 3:1 randomized to placebo). 16 healthy subjects were evaluated in the MAD phase with 7-day dosing at 12.5 or 25 mg. 14 patients with mild to moderate Parkinson's disease (Hoehn & Yahr < 3.0) who remained on Parkinson's medications were evaluated at 50 mg or 100 mg MAD with 7-day dosing. 11 patients with untreated Parkinson's disease (Hoehn & Yahr < 3.0) were evaluated at 50, 100 or 200 mg dosed for up to 11 weeks. Across all 113 healthy subjects or Parkinson's patients who have participated in trials to date, no clinically significant adverse events were observed at any dose or dose duration (Tables 3). No cardiovascular adverse events that were related to IkT-148009 were observed, to include no QTcF prolongation in either male or female subjects. The unblinded, complete adverse event profiles appear in Tables 3. Of 20 total adverse events that occurred in healthy subjects or Parkinson's patients, 17 occurred in subjects or patients treated with active drug, none of clinical significance. Of 8 adverse events seen in untreated Parkinson's patients with up to 11 weeks dosing (Table 3), two adverse events in a

single patient with amylase and lipase laboratory abnormalities were screened to be normal but had elevated values at baseline (pre-dose) and increased to higher levels at the 4 week visit. A second patient experienced gastric pain nausea on first dosing that did not re-occur over 4 weeks.

No serious adverse events have been observed in healthy subjects or Parkinson's patients at any dose or dosing duration.

Table 3: Complete Adverse Event Listing in SAD and MAD studies ofIkT-148009 in Older and Elderly Healthy Subjects ormild-to-moderate Parkinson's patients with up to 11 week dosing.

Category	Dose mg	Dose Duration	#Occurrences Healthy Subjects (N=88)	# Occurrences PD patients (N=25)	Severity
Cardiovascular	75 mg	Single Dose	1 Palpitations[1]		Mild
Gastrointestinal					
	325 mg	Single Dose	2 Diarrhea		Mild
	100 mg	7-day, 1x/day		1 Constipation[2]	Mild
	100 mg	4 wk, 1x/day		1 Elevated Amylase/Lipase[3]	Moderate
	Active, 50 mg	4 wk		1 Gastric pain[4]	Mild
	Active, 50 mg	4 wk		1 Nausea[4]	Mild
Dermatological					
	50 mg	7-day, 1x/day		1 Dermatitis	Mild

[1]Appeared 2 weeks post-dose, no clinical basis found even after following by 3-day Holter monitoring; [2]Appeared one day after last dosing day; [3]Amylase and Lipase abnormalities were asymptomatic. Patient reported regular consumption of alcohol prior to the baseline visit and while enrolled in the trial; [4]Single occurrence on first dose

The most-commonly-observed laboratory abnormalities were sporadic elevations in amylase and/or lipase that occurred in both placebo and actively-dosed subjects. In all cases, elevations of amylase and/or lipase were asymptomatic and did not correlate with gender, dose or dose duration. Amylase and/or lipase elevations are a known side effect of c-Abl inhibitor therapy.[8]

[8] Pezzilli R, Corinaldesi R, Morselli-Labate AM. Tyrosine Kinase Inhibitors and Acute Pancreatitis. J. Pancreas 2010; 11a:291-293.

Pharmacokinetics in Humans

Clinical pharmacokinetics of single doses of IkT-148009 are summarized in Figure 7.

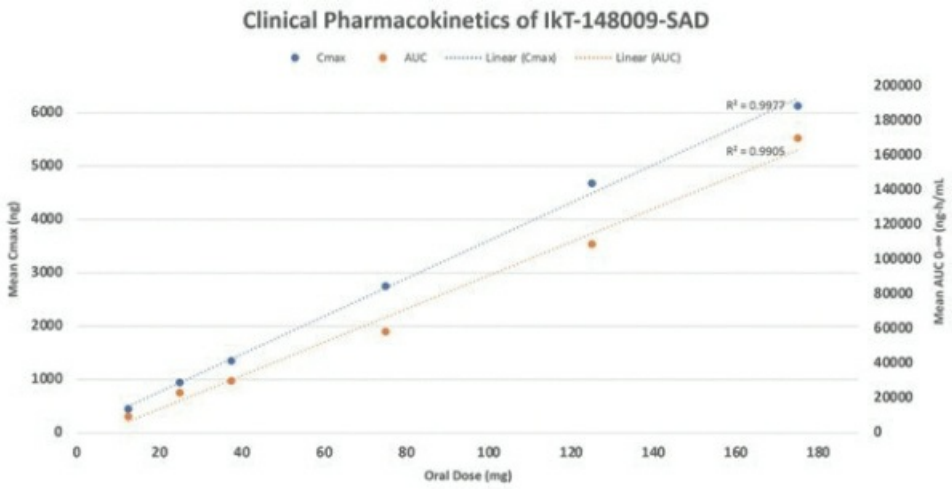


Figure 3: Clinical Pharmacokinetics of IkT-148009 in SAD

In the SAD study, IkT-148009 showed linear dose proportionality as the dose escalated to 175 mg, but plateaued at 250 mg and 325 mg. The half-life of IkT-148009 averaged 23-25 hours, with a Cmax reaching 6130 ng/mL at 175mg and the AUC0-inf reaching 170,000 ng-h/mL. These exposures are deemed to be very high. Multiple dose PK demonstrated a 2-fold accumulation in elderly healthy subjects, with steady-state reached between days 4 and 5. Parkinson's patients, on the other hand, displayed a 1.3 to 1.4-fold accumulation at day 7 and doubling of the dose from 50 to 100 mg resulted in only a 30-40% increase in drug exposure evaluated by Cmax or AUC0-24h at steady-state.

Clinical experience in Parkinson's Patients

Fourteen patients have been dosed at 50 mg or 100 mg IkT-148009 over 7-days once daily (6 active, 2 placebo at 50 mg and 5 active and one placebo at 100 mg). As for healthy subjects of the same age, IkT-148009 appeared to be well-tolerated (Table 3). One case of dermatitis emerged on the first day of dosing in a patient given 50 mg. The dermatitis was treated medically and no reoccurrence was noted nor was dosing disrupted. In Parkinson's patients, one instance of diarrhea and one instance of constipation were observed post dosing. Pharmacokinetics of IkT-148009 in patients suggested the drug was less well absorbed (≈ 40% less) compared to a comparable dose in older healthy subjects as the steady state exposure from 50 mg to 100 mg was less than dose proportional (1.4:1), but exhibited the same half-life with a similar distribution volume and clearance rate.

Eight patients with untreated Parkinson's disease have been dosed at 50 mg, 100 mg or 200 mg for up to 11 weeks. Longer duration of dosing did not result in a more frequent occurrence in laboratory abnormalities or adverse events; amylase and lipase elevations in patients dosed up to 11 weeks were observed in only a single patient.

Clinical Development Going Forward

IkT-148009 restarted its '201' trial in patients with untreated Parkinson's disease following lifting of the FDA full clinical hold in January 2023. The full clinical hold was issued November 7, 2022, following review of our

IND submission to expand use of IkT-148009 to MSA; the IND submission cross-referenced all of the IkT-148009 data in Parkinson's disease, leading to the hold being applied across all the IkT-148009 programs. The FDA lifted the hold for the application of IkT-148009 in Parkinson's in January 2023 and in MSA in March 2023. The 201 trial has restarted with two doses at 50 mg and 100 mg initially while we also measure the steady-state pharmacokinetic profile IkT-148009 at 200 mg in 6 healthy volunteers age 45-70. Upon completion of the 200 mg healthy volunteer study in March 2023 and if no safety concerns arise, we will include the 200 mg dose in the 201 trial. Three untreated Parkinson's patients were dosed at 200 mg for 2 weeks to 8 weeks prior to the trial being halted and none of these patients experienced a clinically meaningful adverse event, so we anticipate including the 200 mg dose into the 201 trial as soon as practicable. Figure 4 summarizes the design and outcome analysis planned for the 201 trial.

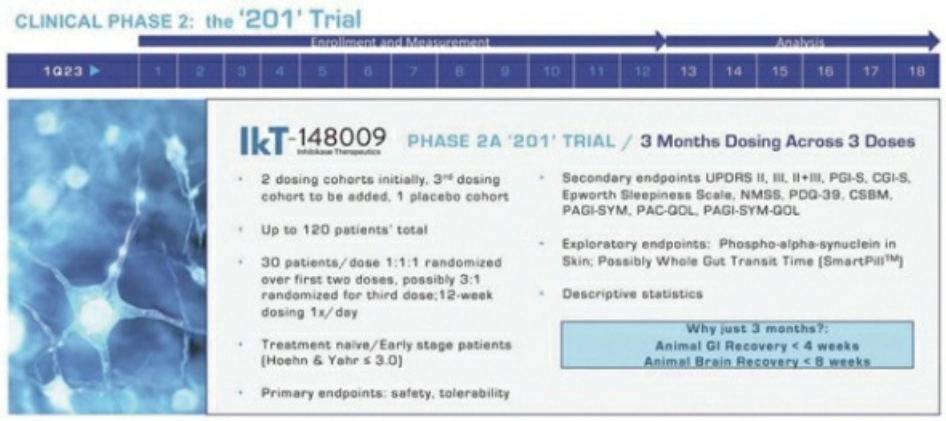


Fig. 4: Design and outcome analysis planned for the Phase 2a 201 trial of IkT-148009 in untreated Parkinson's disease.

In the gut, we will take a unique approach to seeking approval for the GI complications in PD patients. In the GI, prospective and retrospective data using a wireless motility capsule measuring WGTT, a battery of clinical assessment scores and potentially GI biopsies will be used to assess clinical benefit in the GI. The combination of these measures of GI function represents a new approach to evaluating neurological function in PD patients with GI complications. We believe these quantitative measures in the GI tract could facilitate proof-of-concept trials in the future and provide quantitative endpoints from measures in the GI that could augment analysis of trials in the future and provide quantitative endpoints from measures in the GI that could augment analysis of therapeutic benefit in the brain. Trial design and the number of patients we intend to enroll in such studies will be discussed with the FDA in follow-up meetings, to include agreement on the use of GI endpoints in analyzing therapeutic benefit.

We believe simultaneous measures in the brain and GI tract offer an additional development advantage for us. The ability to restore normal GI function implies that PD patients may experience more normal bathroom and/or eating habits. We can think of no more fundamental improvement in quality of life than the ability to eat or to go to the bathroom normally, which is becoming a key metric of therapeutic benefit for PD.

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 eleven companies have been approved to sell generic imatinib in the U.S. In 2020, sales for generic imatinib were approximately $331 million per year across the retail counter, indicative of a potentially robust commercial market for IkT-001Pro. In non-human primates IkT-001Pro displayed 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 Tasigna®), 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 just 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.

Pharmacology of IkT-001Pro in preclinical models

We believe many of the side effects that degrade adherence to imatinib therapy arise from GI distress on absorption, along with degradation that occurs at the gut wall (so-called first-pass metabolism). IkT-001Pro is a chemically modified form of imatinib, which is absorbed intact and enzymatically releases imatinib in the blood (Table 1). Evaluation of the prodrug absorption and distribution in rats demonstrated that the exposure to imatinib is significantly higher overall. We determine this by measuring the Area Under the Curve, or AUC, as illustrated in Table 7.

Table 6: Pharmacokinetic (PK) parameters in male rat at 3 mg/kg/day orally (n=3) and stability in human plasma for imatinib prodrugs

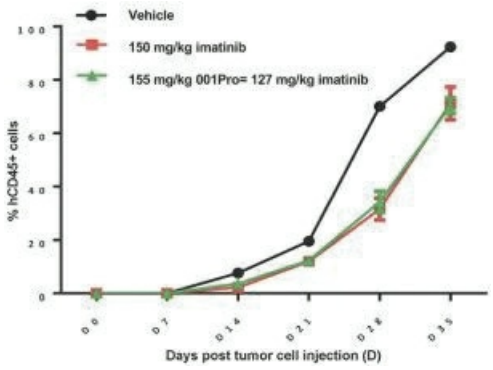
Drug	T_{max} (hr)	C_{max} (nM)	AUC (ng-h/mL)	Elimination $T_{1/2}$ (h)	Prodrug $t_{1/2}$ Distribution volume (L/kg)	Prodrug $t_{1/2}$ Human Plasma (min)(1)
Imatinib	2	323.3	1753	2.7	1.1	N/A
IkT-001Pro	4	387	2712	2.0	3	<5

(1) The half-life of the prodrug is essentially the same in rat, monkey and human plasma.

We have evaluated IkT-001Pro in a dose-range-finding study and in a pivotal 28-day GLP toxicology study in monkeys. One of the principal measurements we make in a toxicology study is the No Observed Adverse Event Level, or NOAEL. The NOAEL is the dosing level at which no meaningful toxicity is observed. For IkT-001Pro, the NOAEL is 5-fold higher for IkT-001Pro relative to imatinib given alone. The higher NOAEL means that the prodrug drug suppressed some side effects that normally arise from imatinib itself. In these studies, we observed that all the GI and other on-dosing side effects were suppressed at the NOAEL dose.

Efficacy of IkT-001Pro in preclinical animal models of leukemia

We measured the efficacy of imatinib therapy versus the prodrug in a patient-derived model of leukemia by transferring the liquid tumor of a human patient into an immune-suppressed mouse, giving the mouse a human leukemia. When we compared the dose of IkT-001Pro in this animal model to the dose of imatinib required to observe the same effect, we determined that we could deliver 15% less imatinib than if we had dosed the animals with imatinib alone (Fig 5).[9] We believe these results suggest that IkT-001Pro delivers imatinib into the body more efficiently than imatinib alone.



[9] Jabbour E., Kantarjian H. (2014) Chronic myeloid leukemia: 2014 update on diagnosis, monitoring, and management. Am. J. Hematol.89:548-556.

Fig. 9: Comparison of tumor control for imatinib and IkT-001Pro. 150 mg/kg imatinib or 155 mg/kg IkT-001Pro were dosed daily into 15 mice per group and compared to vehicle control. Dosing began on the 8th day after tumor cell inoculation into the tail vein with human, patient-derived leukemia cells, which could be followed with the cell surface marker CD45. As is readily apparent, tumor control by imatinib and IkT-001Pro were identical even though IkT-001Pro delivered 15% less imatinib relative to imatinib alone. This is due to the mass difference between imatinib and IkT-001Pro. These results confirm the observations made with respect to the AUC or drug exposure per unit mass of prodrug vs. imatinib alone.

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

Through pre-IND discussions with the FDA Division of Hematology, we believe approval of IkT-001Pro could be achieved through the 505(b)(2) regulatory pathway. The IND was filed in August 2022 and the Study May Proceed letter allowing clinical entry was received in September 2022. In this instance, clinical development prior to the New Drug Application meeting is a measure of bioequivalence, which began in mid-December 2022. Four cohorts will be measured at 300, 400, 500 and 600 mg IkT-001Pro freebase delivered as a combination of film-coated tablets of 100 mg or 400 mg strength. The 300 mg dose enrolled three healthy volunteers for a single dose of IkT-001Pro and measurement of the pharmacokinetic (PK) profile over 96 hours along with a batter of safety evaluations. PK evaluation from these three volunteers revealed that IkT-001Pro delivered the expected amount of the active ingredient imatinib, and no side effects or clinically meaningful laboratory abnormalities or cardiovascular risks were observed. The 400, 500 and 600 mg IkT-001Pro freebase cohorts will involve eight healthy subjects in a single period crossover study wherein in all eight will first receive a single dose of the specified dose of IkT-001Pro, have blood drawn for PK measures and then 'washout' for seven days before receiving a single dose of commercial 400 mg imatinib mesylate. As for IkT-001Pro, the 96-hour PK blood samples will be drawn for PK analysis and comparison to the PK analysis of IkT-001Pro. The 300, 400 and 500 mg dose cohorts have been completed as of the date of this prospectus.

Upon completion of the 600 mg dose, the dose of IkT-001Pro equivalent to 400 mg imatinib mesylate will be computed from the PK data across all four cohorts and then a confirmatory study in 32 healthy volunteers will be performed in a two-period crossover study. In the two-period crossover study, 16 healthy subjects will first take Imatinib mesylate and the other 16 healthy subjects will be given the equivalent dose of IkT-001Pro. Following the 7-day washout, the subjects on 400 mg imatinib mesylate will switch to IkT-001Pro, while the subjects that were first administered IkT-001Pro will switch to 400 mg imatinib mesylate. If the confirmatory study validates the computed dose of IkT-001Pro equivalent to 400 mg imatinib mesylate, we will then request a meeting with the FDA to discuss the parameters for the New Drug Application or NDA. Coincident with that meeting, we plan to evaluate the safety benefit of IkT-001Pro in a superiority trial in existing patients on 400-mg imatinib mesylate to further validate the medical advantage of IkT-001Pro over standard-of-care 400 mg imatinib mesylate.

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 Dementia with Lewy Body or DLB, and Progressive Multifocal Leukoencephalopathy or PML.

Dementia with Lewy Body (DLB)

DLB is a Parkinson's-like disease characterized by alpha-synuclein aggregates, c-Abl activation and alpha-synuclein aggregate chemical modification much like that found in Parkinson's disease. DLB is diagnosed by observation of a progressive onset of cognitive impairment that may be followed by motor function deficits and characterized morphologically by widespread cortical and subcortical α-synuclein/ Lewy body plus ß-amyloid and tau pathologies. The clinical features of DLB include cognitive impairment, parkinsonism, visual hallucinations, and fluctuating attention. PD and DLB are both Lewy Body disorders. PD and DLB share many features as the disease progresses, and therefore it is not surprising that PD and DLB share the involvement of

alpha-synuclein aggregates and c-Abl activation. Most striking about DLB versus PD, however, is that DLB often occurs concomitant with the pathology associated with Alzheimer's Disease (AD), suggesting a mechanistic linkage between Parkinson's and Alzheimer's Disease. While it is possible to distinguish PD from DLB in the clinic using diagnostic procedures, it is not possible to create independent pre-clinical models for DLB and for PD. Unlike other alpha-synuclein-related disorders, such as MSA, there are no animal models that permit evaluation of cognitive function with no motor dysfunction. Therefore, we are using the properties determined for IkT-148009 to screen additional molecules from the 148x series and evaluating pharmacokinetics in animals to identify candidate(s) from the 148x series that share brain penetration, toxicology and other characteristics that are similar with IkT-148009. The development of an animal model to assess the therapeutic utility in DLB is not necessary, because we believe the characteristics of a molecule suitable for treatment of DLB are similar to one used to treat PD given the significant overlap in disease pathology and clinical features. Rather, we are evaluating which of the 148x series molecules is the best candidate to follow IkT-148009 into the clinic and planning the pre-clinical studies, which will be required prior to evaluating the molecule clinically in patients with a formal diagnosis of DLB.

Progressive Multifocal Leukoencephalopathy (PML)

PML emerged as an unusual form of cognitive decline during the AIDS epidemic of the 1980s, arising from the migration and lytic infection of the John Cunningham virus, or JCV, from its reservoirs in the kidney and bone marrow not the brain. With the advent of antiretroviral therapy that restored normal immune responses to viral infection in patients with HIV infection, the first reports of progressive multifocal leukoencephalopathy (PML) in patients since the era of the AIDS epidemic occurred during Phase 3 clinical trials evaluating natalizumab treatment for relapsing remitting multiple sclerosis. Natalizumab is a monoclonal antibody against α4ß1 and α4ß7 integrins that blocks lymphocyte surveillance in the brain and can prevent multiple sclerosis-related clinical relapses. The co-occurrence of PML and multiple sclerosis was unanticipated. Once JCV enters the CNS, JCV induces a lytic infection of oligodendrocytes and astrocytes, which is fatal in approximately 50% of cases. The initial prevalence of natalizumab-associated PML in patients with multiple sclerosis was estimated to be 1 in 1000. However, as more PML cases emerged among natalizumab-treated patients, with substantial morbidity in survivors, the prevalence of PML among patients treated with natalizumab for more than 24 months who also carried antibody evidence of JCV infection and previous immunosuppressant exposure, climbed to at least 1 in 70. Analysis of polyomavirus infection and reproduction in host cells revealed that polyomaviruses like JCV are dependent on c-Abl for viral entry into the cells it is going to infect.[10] This suggests to us that c-Abl inhibitors could be an effective anti-viral strategy to block productive JCV infection inside and outside of its reservoirs in a living organism.

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, Roger Rush, Ph.D., who has led IND-enabling programs for ground-breaking medications, like the Hepatitis C compound portfolio of Idenix, which was sold to Merck & Co., and Dr. Surendra Singh who has extensive experience in process scale and commercial manufacturing of drug substances. We have engaged Clintrex

[10] Swimm AI, Bornmann W, Jiang M, Imperiale MJ, Lukacher AE, Kalman D. (2010) Abl family tyrosine kinases regulate sialylated ganglioside receptors for polyomavirus. *J. Virol*. 84, 4243-4251.

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 to 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 Kieburtz 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 RAMPTM, 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 collaboration and 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 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 deployed to develop c-Abl inhibitors capable of maintaining therapeutic concentrations in the brain, 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 March 2017, the National Institute of Allergy and Infectious Disease, an Institute of the National Institutes of Health, awarded us an additional $2,000,000 to continue our development of small molecule therapeutics to treat JCV infection in the brain.
- In March 2017, the Michael J. Fox Foundation awarded us $433,729 to screen our novel c-Abl protein kinase inhibitors in a mouse model of Parkinson's disease.
- In June 2017, we believe we came to an understanding with the FDA on the requirements for approval for IkT-001Pro, a prodrug of imatinib, for the treatment of stable-phase patients with CML using a product with a potential for significant reduction of side effects under the FDA 505(b)(2) regulations.
- In September 2017, the National Institute of Neurological Disease and Stroke, an Institute of the National Institutes of Health, awarded us $3,108,583 to advance our novel c-Abl inhibitors as disease modifying therapies for Parkinson's disease and related disorders.
- In March 2018, we opened our pre-IND discussion with the FDA for the application of our novel c-Abl inhibitor IKT-148009 for the treatment of Parkinson's disease.
- 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 ofIkT-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 forIkT-148009. First dosing of patients for treatment of PD commenced on February 16, 2021. Clinical development of IkT-148009 for the GI complications in PD patients will cross-reference the first human study of 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 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 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 novelc-Abl inhibitor IkT-148009 in an animal model of Multiple System Atrophy.
- In May 2022, we commenced a Phase 2a trial ofIkT-148009 in patients with untreated Parkinson's disease.
- In August 2022, we filed our IND application forIkT-001Pro to commence clinical development for the treatment of Stable-phase CML.
- In September 2022, we filed our IND application for the application ofIkT-148009 to commence clinical development ofIkT-148009 in Multiple System Atrophy ("MSA").
- In November 2022, we received a full clinical hold from the FDA onIkT-148009 programs in PD and MSA.
- In December 2022, we filed our Complete Response to the clinical hold onIkT-148009 in PD with the U.S. FDA.
- In January 2023, we received notice of the lifting of the clinical hold onIkT-148009 in PD.
- In January 2023, we 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 onIkT-148009 in MSA.

Regulatory and Clinical Experiences

From September 2014 through September 2016, we conducted twonon-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 IkT-148009. In February 2021, we

[11] Werner, M.H. and Huang, D. (2016) Natalizumab-treated patients at high risk for PML persistently excrete JC polyomavirus. J. Neurovirol. 22:871.

began our Phase 1 trial of 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 2a studies in 2022. In October 2022, an Investigational New Drug Application ("IND") to expand use of IkT-148009 into the Parkinson's-related disease MSA was filed with the FDA. On November 7, 2022, following review of the IND forIkT-148009 as a treatment for MSA, the FDA notified the Company that it was placing the IkT-148009 programs for Parkinson's disease and MSA on clinical hold. The FDA lifted the full clinical hold in January 2023 for the Parkinson's programs and in March 2023 for the MSA program.

Also in 2022, we commenced clinical development ofIkT-001Pro.

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 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 developso-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.

We have received economic development grants and loans totaling $455,550 through the Georgia Research Alliance, or GRA, anot-for-profit entity of the State of Georgia. Under the terms of these grants and loans, we had to in-license intellectual property from a State of Georgia research university, such as Emory University, and attempt to translate this intellectual property into a useful medical product. As part of the terms and conditions of these grants and loans, the Company had to meet certain development milestones or establish that the in-licensed technology could not lead to a useful medical product. We complied with all of the terms of these grants and loans. The GRA loans could further be converted into company stock, based on the fair market value of our common stock at the time of conversion. GRA elected to convert the outstanding amount on its two loans on May 31, 2018 into 47,318 shares of our Common Stock.

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 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 the IkT-001Pro oncology product, 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. However, only we have the right to commercialize a Company Compound unless we formally abandon our interests.

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

As consideration for its services, Sphaera has received a fixed fee of $160,000 and is entitled to the following milestone payments upon achievement of specified milestones:

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	$ 5,625,000

No milestone payments have been made to Sphaera, and the Company does not anticipate that any milestone payments will be made to Sphaera. Sphaera is also entitled to royalty payments of a percentage of annual net sales and sublicenses ranging in the mid-single digits for applicable products.

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

Our clinical research organization partnership is with Cognitive Research Corporation, or CRC, through a Masters Services Agreement that includes medical, analytical and pharmacy support services along with clinical research management and data handling according to a statistical analysis plan, although CRC may not be

retained for future trials depending on the needs of future individual programs. We use the Hassman Research Institute as a single clinical evaluation site which is managed by CRC and Inhibikase clinical development staff. 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 are 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 Pharmaceuticals Co., Ltd., a subsidiary of WuXi AppTec Co., Ltd., which is based in China. We have contracted solid dosage formulations of 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. Several large and specialty pharmaceutical companies, including Prothena Corporation plc, Roche Holdings AG, Biogen Inc., Neurimmune Holding AG, UCB S.A., Neuropore Therapies, Inc., Sanofi S.A., Novartis A.G. and Takeda Pharmaceutical Company Ltd. are developing potentially disease modifying therapeutics for PD and are in various stages of clinical trials. Denali Therapeutics Inc. and Prevail Therapeutics Inc. are pursing 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, andknow-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 Related to Our 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 and in-licensed compounds were funded in whole or in part by the U.S. government and are therefore subject to federalmarch-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 February 1, 2023, our patent portfolio included: (i) eight issued patents and two pending patent applications in the United States and (ii) eight issued foreign patents and seven 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 six issued U.S. patents and one 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, and U.S. Patent no. 11,407,747, 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 and Australia, and pending patent applications in Japan, Australia, 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, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. 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 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 timeframes 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 preliminary 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 a U.S. Food and Drug Administration (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 recordkeeping, 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 March 14, 2023, we had six 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 purposes of our equity incentive plan is to attract, retain and motivate selected employees, consultants and directors through the granting of stock-based compensation awards.

Facilities

Our corporate headquarters are located in Atlanta, Georgia, where we lease a single corporate office. Additionally, we have approximately 4,200 square feet of office space in Lexington, Massachusetts which we use as office and conference spaces for our team, most of whom are based in the surrounding area. It is anticipated that these distinct facilities will meet our needs for the foreseeable future.

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.

MANAGEMENT

Executive Officers and Directors

The following table sets forth the names, ages and positions of our executive officers and directors as of March 14, 2022:

Name	Age	Position
Executive Officers:		
Milton H. Werner, Ph.D.	60	President, Chief Executive Officer and Director
Joseph Frattaroli, C.P.A.	61	Chief Financial Officer
Non-Employee Directors:		
Gisele Dion[1][2][4]	56	Director
Roy Freeman, M.D.[2][3]	71	Director
Paul Grint, M.D.[1][2][3][5]	65	Director
Dennis Berman[1][3][6]	72	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

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

Roger Rush, Ph.D. has been our Head of Preclinical Research since January 2015 and is an experienced veteran of the pharmaceutical industry with over 30 years of experience working in the United Kingdom and U.S. for small and large pharmaceutical companies and contract research organizations, and is now based in the greater Boston area. Dr. Rush has been a principal of Allon Preclinical Consulting, LLC since February 2015. From March 2012 to December 2014, he was Vice President Preclinical Development for Idenix Pharmaceuticals, Inc., a pharmaceutical company and wholly-owned subsidiary of Merck & Company, Inc., where he managed the DMPK, toxicology and discovery research that lead to the identification of lead molecules to treat the Hepatitis C virus. His major career focus has been on preclinical research and development, safety assessment and the translation of discovery research molecules into clinical development. He has contributed to over 20 IND, CTA and product license submissions and approved drugs including nicardipine (Cardene), ranolazine (Ranexa), Foscan, and zileuton (Zyflo CR). His work has spanned numerous therapeutic areas, including anti-inflammatory, anti-allergy, arthritis, anti-infectives, CNS, cardiovascular, oncology, genitourinary and anti-hyperlipidemics. He received his B.Sc. and Ph.D. in Biochemistry from the University of Surrey in the United Kingdom.

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 professional of Inhibikase 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 aco-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 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 makes 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 (ACTTION), 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 on the board of directors of Cutaneous Neurodiagnostic Life Sciences. 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 alpha-synucleinopathies. He has been a principal investigator on many neurodegenerative diseases and neuropathic pain clinical trials. He has authored more than 280 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 two 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 a board member at January Therapeutics, Cardea Bio and Synedgen. 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 131,123 shares of our common stock with an exercise price of $2.31 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 131,123 shares of our common stock with an exercise price of $2.31 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 "Management."

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 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, which 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 Connelly 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 2023.

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 Rule10A-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 Rule10C-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."

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.

Director Compensation

The following table presents the total compensation received by each of ournon-employee directors during the year ended December 31, 2022.

Name	Fees Earned or Paid in Cash ($)	Option Awards ($)(1)	Total ($)
Mr. Dennis Berman	58,000	20,623	78,623
Dr. Roy Freeman	49,000	20,623	69,623
Dr. Paul Grint	64,000	20,623	84,623
Ms. Gisele Dion (2)	21,667	37,225	58,892
Ms. Elizabeth O'Farrell (3)	43,333	—	43,333

(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 include a risk-free interest rate of 2.89 to 3.45 percent, expected volatility of 86.31 to 86.81 percent, expected term of 4 to 4.25 years and an expected dividend yield of zero percent. These amounts do not correspond to the actual value that may be recognized by the directors upon vesting of the applicable awards.
(2) Ms. Dion joined the Company's board of directors on September 1, 2022.
(3) Ms. O'Farrell retired from the Company's board of directors and as audit committee chair on September 1, 2022.

Our board of directors has approved the following compensation program for ournon-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 asnon-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, increased from $5,000 per year, effective January 1, 2022 (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, increased from $5,000 per year, effective January 1, 2022;
- $4,000 per year additionally for service as member of the corporate governance and nominating committee, increased from $3,000 per year, effective January 1, 2022 (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 will be granted an initial stock option grant of 60,000 option shares with 50% vesting on each of the first two anniversaries of the date of grant and each current non-employee director commencing in 2022 will be granted an annual stock option grant of 40,000 option shares, with vesting on the earlier of the one year anniversary of the date of grant or the day prior to the next annual meeting of stockholders.

On June 24, 2022 each non-employee director received an annual grant of 40,000 non-qualified stock options with a grant date fair value of $20,623, which options will vest one year after the grant date, subject to the grantee's continued service through that date. In addition, on September 1, 2022, in connection with her appointment to the board of directors, Ms. Dion received an initial stock option grant of 60,000 option shares with 50% vesting on each of the first two anniversaries of such grant date. The Company intends 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, and, in January 2021, received a one-time stock option grant in respect of 11,438 shares of our common stock. Unlike other scientific advisory board members, we have ongoing pre-clinical research collaborations with Drs. Ted and Valina Dawson and therefore they each received a stock option grant in 2017 in respect of 131,123 shares of our common stock with a five-year vesting period and an exercise price of $2.31. 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.

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, 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, 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 prospectus does not include or incorporate by reference the information on our website into this prospectus. 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.

EXECUTIVE COMPENSATION

Our named executive officers for 2022 which consist of our principal executive officer and the 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 Officer

Summary Compensation Table

The following table sets forth information regarding the compensation of our named executive officers for the years ended December 31, 2022 and December 31, 2021:

Name and Principal Position	Year	Salary ($)	Bonus ($)	Option Awards ($)(1)	Non-Equity Incentive Plan Compensation ($)(2)	All Other Compensation ($)(3)	Total ($)
Milton H. Werner, Ph.D.	2022	500,833	—	85,865	140,250	17,107	744,055
President and Chief Executive Officer	2021	455,000	—	—	138,548	17,107	610,655
Joseph Frattaroli, C.P.A.	2022	395,833	—	42,932	136,000	—	574,765
Chief Financial Officer	2021	375,000	—	—	112,500	—	487,500

(1) The amount represents the aggregate grant date fair value of the option 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 include a risk-free interest rate of 1.7 percent, expected volatility of 84.15 percent, expected term of 4.5 years and an expected dividend yield of zero percent.

(2) Amounts represent awards to our named executive officers under our annual performance-based cash incentive program. Annual cash incentive compensation for 2022 was earned in 2022 and paid in 2023, annual cash incentive compensation for 2021 was earned in 2021 and paid in 2022

(3) The amount represents $5,023 for life insurance policy premiums and $12,084 in automobile expenses for the years ended December 31, 2022 and 2021.

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, 2022:

	Option Awards					
Name	Grant Date	Number of Securities Underlying Unexercised Options (#) Exercisable(1)	Number of Securities Underlying Unexercised Options (#) Unexercisable(2)	Equity incentive awards: number of securities underlying unexercised unearned options (#)	Option Exercise Price ($)	Option Expiration Date
Milton H. Werner	11/1/2015	21,854	—	—	2.31	11/1/2025
	11/1/2016	21,854	—	—	2.31	11/1/2026
	11/1/2017	21,854	—	—	2.31	11/1/2027
	11/1/2018	21,854	—	—	4.79	11/1/2028
	11/1/2019	21,854	—	—	5.57	11/1/2029
	12/22/2020 (2)	66,667	33,333	—	10.00	12/22/2027
	3/7/2022 (3)	—	125,000	—	1.07	3/7/2029
	3/7/2022 (4)	—	250,000	—	1.07	3/7/2029
Joseph Frattaroli	8/25/2020	21,854	—	—	5.90	8/25/2027
	8/25/2020	150,000	—	—	5.90	8/25/2027
	12/22/2020 (2)	66,667	33,333	—	10.00	12/22/2027
	3/7/2022 (3)	—	62,500	—	1.07	3/7/2029
	3/7/2022 (4)	—	125,000	—	1.07	3/7/2029

(1) The grant of 150,000 options to Mr. Frattaroli with a grant date of August 25, 2020 was issued to Flagship Consulting, Inc. ("Flagship"). Flagship is owned and controlled by Mr. Frattaroli.

(2) One third of these grants vested and became exercisable on the first anniversary of the closing of our initial public offering (i.e. December 28, 2021) and the remainder will vest and become exercisable in 24 equal monthly installments thereafter (commencing with January 1, 2022), subject generally to continued service through each vesting date.

(3) One third of these grants 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 continued service through each vesting date.

(4) These options are subject to performance vesting and will vest and become exercisable once the performance conditions have been met. There is no assurance that the performance conditions will be met and therefore some or all of these options may never vest or become exercisable. As at December 31, 2022 no performance conditions were met.

Employment Arrangements with Our Named Executive Officers

Milton H. Werner, Ph.D. Employment Agreement

Pursuant to Dr. Werner's employment agreement (the "Werner Employment Agreement"), Dr. Werner receives an annual base salary of $510,000 and is eligible to receive an annual performance cash bonus with a target amount equal to 50% of his annual base salary, which cash bonus 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 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.

Pursuant to the Werner Employment Agreement, Dr. Werner is subject to aone-year post-termination non-compete and non-solicit of employees and clients. 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" other than in connection with a change in control, 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; (ii) payment of any annual bonus accrued for the year prior to termination (to the extent not already paid); (iii) payment of a pro-rated annual bonus (pro-rated based on the number of days Dr. Werner was employed during the year) for the year of termination based on actual performance through the end of the year and paid when bonuses are paid to other senior executives of the Company; (iv) reimbursement of COBRA premiums for up to 12 months; and (v) full vesting for 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.

In the event of a termination of Dr. Werner's employment by the Company without "cause" or by Dr. Werner for "good reason" within 12 months following 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; (ii) payment of any annual bonus accrued for the year prior to termination (to the extent not already paid); (iii) an amount equal to his-then target annual bonus; (iv) payment of a pro-rated target annual bonus (pro-rated based on the number of days Dr. Werner was employed during the year) for the year of termination; (v) reimbursement of COBRA premiums for up to 18 months; and (vi) full vesting for 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.

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 receive full vesting for 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 by the Company without "cause", by Dr. Werner for "good reason" or due to 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 (A) a six-month period in the event of a termination that is not in connection with a change in control, or (B) 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: the conviction of or plea of nolo contendere to a felony; the commission of fraud, misappropriation or embezzlement against any person; the theft or misappropriation of Company property; the breach of the Werner Employment Agreement by Dr. Werner (subject to a cure right); the willful or gross neglect by Dr. Werner of his duties (subject to a cure right); willful or gross misconduct in Dr. Werner's performance of his duties (subject to a cure right); or the willful violation of any material Company policy (subject to a cure right).

"Good Reason" means generally: a material diminution in authority, duties or responsibilities; a material diminution in base salary that persists for longer than 12 months; or a material breach of the Werner Employment Agreement by the Company. For good reason to apply, Dr. Werner must provide notice to the Company within 90 days of the initial existence of one of the above conditions, the Company fails to cure such condition within 30 days, and Dr. Werner terminates his employment within 180 days following the initial existence of the condition.

"Change in Control" means generally: 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); 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 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

Pursuant to Mr. Frattaroli's employment agreement (the "Frattaroli Employment Agreement"), Mr. Frattaroli receives an annual base salary of $410,000 (increased effective March 1, 2023 from $400,000) and is eligible to receive a discretionary annual target performance cash bonus with a target amount equal to 40% of his annual base salary, which cash bonus 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, budgeting and successful organizational growth.

Pursuant to the Frattaroli Employment Agreement, Mr. Frattaroli is subject to aone-year post-termination non-compete and non-solicit of employees and clients. 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" other than in connection with a change in control, Mr. Frattaroli is entitled to receive: (i) severance payments equal to nine months of his base salary, paid out in equal installments in accordance with the Company's normal payroll practices; (ii) payment of any annual bonus accrued for the year prior to termination (to the extent not already paid); (iii) payment of a pro-rated annual bonus (pro-rated based on the number of days Mr. Frattaroli was employed during the year) for the year of termination based on actual performance through the end of the year and paid when bonuses are paid 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" within 12 months following a change in control, Mr. Frattaroli is entitled to receive: (i) severance payments 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 termination (to the extent not already paid); (iii) payment of a pro-rated annual bonus (pro-rated based on the number of days Mr. Frattaroli was employed during the year) for the year of termination based on target; (iv) an amount equal to his-then target annual bonus; (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 by the Company without "cause", by Mr. Frattaroli for "good reason" or due to 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 (A) a nine-month period in the event of a termination that is not in connection with a change in control, or (B) 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: the commission of an act of disloyalty, dishonesty, breach of trust, fraud, misconduct, bad faith, embezzlement, misappropriation of Company assets, or destruction of Company property; gross negligence in the performance of employment duties; refusal, failure or willful nonfeasance to perform employment duties; failure to comply with Company policy (subject to a cure right); conduct which is materially detrimental to the reputation, goodwill or business operation of the Company; the conviction for, or plea of nolo contendere, to a felony; or 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 meanings as those provided in the Werner Employment Agreement, as described above.

Equity Compensation

On March 7, 2022 we granted an option to purchase 375,000 and 187,500 shares of our common stock under the 2020 Plan to Milton H. Werner and Joseph Frattaroli respectively. 250,000 and 125,000 of these options are subject to performance vesting in relation to Milton H. Werner and Joseph Frattaroli respectively. These grants have a seven year term and exercise price of $1.07 per share. One third of the time vested grants 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 continued service through each vesting date

On March 1, 2023 we granted an option to purchase 315,000 and 135,00 shares of our common stock under the 2020 Plan to Milton H. Werner and Joseph Frattaroli respectively. 105,000 and 45,000 of these options are subject to performance vesting in relation to Milton H. Werner and Joseph Frattaroli respectively. These grants have a seven year term and exercise price of $0.7390 per share. One third of the time vested grants 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 continued service through each vesting date.

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 entering into of one or more strategic partnerships, the adequacy of the Company's working capital, investor relations, financial reporting and operations, budgeting and successful organizational growth.

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, 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 plan. The Simple IRA plan authorizes employer safe harbor matching contributions equal to 3% of covered compensation for eligible employees. The Simple IRA 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 plan and earnings on those contributions are not taxable to the employees until distributed from the Simple IRA plan.

Our named executive officers who are full time employees are eligible to participate in our medical and dental insurance plans, which are paid by the Company at 90% following the completion of the December 2020 initial public offering, 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 2022 for automobile expenses.

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

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 "Management" and "Executive Compensation," and the registration rights described in the section titled "Description of Capital Stock — Registration Rights," there was no transaction since January 1, 2021 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 "Management" and "Executive Compensation," and the registration rights described in the section titled "Description of Capital Stock — Registration Rights."

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 14, 2022 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 28,977,238 shares of our common stock outstanding on March 14, 2023. We have deemed shares of our common stock subject to stock options that are currently exercisable or exercisable within 60 days of March 14, 2023, 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.

	Shares Beneficially Owned	
Name of Beneficial Owner	Shares	Percentage
Named Executive Officers and Directors		
Milton H. Werner, Ph.D.(1)	5,573,802	19.1%
Joseph Frattaroli, C.P.A.(2)	324,806	1.1%
Dennis Berman(3)	160,625	*
Roy Freeman, M.D.(4)	160,625	*
Paul Grint, M.D.(5)	160,625	*
Gisele Dion	—	*
All executive officers and directors as a group (six persons)	6,380,483	21.3%
5% Stockholders		
Daniel Kalman, Ph.D.(6)	1,748,313	5.7%

* Represents beneficial ownership of less than one percent.

(1) Consists of (a) 5,335,370 shares held of record by Milton H. Werner, Ph.D. and (b) 238,432 shares underlying options exercisable within 60 days of March 14, 2023.

(2) Consists of (a) 48,091 shares held of record by Flagship Consulting, Inc., an entity controlled by Mr. Frattaroli, (b) 3,948 shares held directly and (c) 272,767 underlying options exercisable within 60 days of March 14, 2023.

(3) Consists of 160,625 shares underlying options exercisable within 60 days of March 14, 2023.

(4) Consists of 160,625 shares underlying options exercisable within 60 days of March 14, 2023.

(5) Consists of 160,625 shares underlying options exercisable within 60 days of March 14, 2023.

(6) Daniel Kalman reports sole voting power with respect to 1,748,313 shares of common stock and sole dispositive power with respect to 1,748,313 shares of common stock. The address for Daniel Kalman is 3243 Wake Robin Trail, Atlanta, Georgia 30341. For information regarding Daniel Kalman, we have relied solely on the Schedule 13G filed with the SEC by Daniel Kalman on March 23, 2021.

DESCRIPTION OF CAPITAL STOCK

The following descriptions of our capital stock and certain provisions of our amended and restated certificate of incorporation and amended and restated bylaws are summaries and are qualified by reference to the amended and restated certificate of incorporation and the amended and restated bylaws. Copies of these documents are filed with the SEC as exhibits to our registration statement, of which this prospectus forms a part.

Our authorized capital stock consists of 110,000,000 shares of capital stock, par value $0.001 per share, of which:

- 100,000,000 shares are designated as Common Stock; and
- 10,000,000 shares are designated as preferred stock.

As of March 14, 2023, there were 28,977,238 shares of our Common Stock outstanding held by 14 stockholders of record. On August 24, 2020, we effected a 1-for-1.14396 reverse stock split of the issued and outstanding shares of our common stock. Except as otherwise indicated, all of the Common Stock information in this prospectus gives effect to the reverse stock split.

Authorized Capitalization

Common Stock

Voting Rights

Each holder of Common Stock is entitled to one vote for each share on all matters submitted to a vote of the stockholders, including the election of directors. Our amended and restated certificate of incorporation and amended and restated bylaws do not provide for cumulative voting rights. Because of this, the holders of a plurality of the shares of Common Stock entitled to vote in any election of directors can elect all of the directors standing for election, if they should so choose. With respect to matters other than the election of directors, at any meeting of the stockholders at which a quorum is present or represented, the affirmative vote of a majority of the voting power of the shares present in person or represented by proxy at such meeting and entitled to vote on the subject matter shall be the act of the stockholders, except as otherwise required by law. The holders of a majority of the stock issued and outstanding and entitled to vote, present in person or represented by proxy, shall constitute a quorum for the transaction of business at all meetings of the stockholders.

Dividends

Subject to preferences that may be applicable to any then-outstanding preferred stock, holders of our common stock are entitled to receive dividends, if any, as may be declared from time to time by our board of directors out of legally available funds.

Liquidation

In the event of our liquidation, dissolution or winding up, holders of our Common Stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of our debts and other liabilities and the satisfaction of any liquidation preference granted to the holders of any then-outstanding shares of preferred stock.

Rights and Preferences

Holders of our Common Stock have no preemptive, conversion, subscription or other rights, and there are no redemption or sinking fund provisions applicable to our Common Stock. The rights, preferences and privileges of the holders of our Common Stock are subject to and may be adversely affected by the rights of the holders of shares of any series of our preferred stock that we may designate in the future.

Fully Paid and Non-assessable

All of our outstanding shares of Common Stock are, and the shares of Common Stock to be issued in this offering, upon payment and delivery in accordance with the underwriting agreement, will be fully paid and non-assessable.

Preferred Stock

Our board of directors has the authority, without further action by the stockholders, to issue up to 10,000,000 shares of preferred stock in one or more series and to fix the rights, preferences, privileges and restrictions thereof. These rights, preferences and privileges could include dividend rights, conversion rights, voting rights, redemption rights, liquidation preferences, sinking fund terms and the number of shares constituting any series or the designation of such series, any or all of which may be greater than the rights of Common Stock. No shares of preferred stock are outstanding, and we have no present plan to issue any shares of preferred stock.

Options

The intrinsic value of all in the money outstanding options as of December 31, 2022 was approximately $0.3 million, based on the closing price of our common stock of $0.50 per share at December 31, 2022, all of which is related to vested options.

Common Warrants

Duration and Exercise Price

The Common Warrants have an exercise price of $0.75 per share. The Common Warrants were immediately exercisable upon issuance and are exercisable until January 27, 2028. The exercise price and number of shares of Common Stock issuable upon exercise are subject to appropriate adjustment in the event of share dividends, share splits, reorganizations or similar events affecting our shares of Common Stock. The Common Warrants were issued in certificated form only.

Exercisability

The Common Warrants are exercisable, at the option of each holder, in whole or in part, by delivering to us a duly executed exercise notice accompanied by payment in full for the number of shares of Common Stock purchased upon such exercise (except in the case of a cashless exercise as discussed below). A holder (together with its affiliates) may not exercise any portion of such holder's warrants to the extent that the holder would own more than 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding shares of Common Stock immediately after exercise, except that upon at least 61 days' prior notice from the holder to us, the holder may increase the amount of ownership of outstanding shares of Common Stock after exercising the holder's Common Warrants up to 9.99% of the number of shares of Common Stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the Common Warrants.

Cashless Exercise

If at the time of exercise of the Common Warrant there is no effective registration statement registering, or the prospectus contained therein is not available for the resale of the shares of Common Stock issuable upon exercise of the Common Warrant, then the Common Warrants will only be exercisable on a "cashless exercise" basis under which the holder will receive upon such exercise a net number of common shares determined according to a formula set forth in the Common Warrants.

Fundamental Transactions

In the event of any fundamental transaction, as described in the Common Warrants and generally including any merger with or into another entity, sale of all or substantially all of our assets, tender offer or exchange offer, or

reclassification of our shares of Common Stock, then upon any subsequent exercise of a Common Warrant, the holder will have the right to receive as alternative consideration, for each share of Common Stock that would have been issuable upon such exercise immediately prior to the occurrence of such fundamental transaction, the number of shares of Common Stock of the successor or acquiring corporation or of our Company, if it is the surviving corporation, and any additional consideration receivable upon or as a result of such transaction by a holder of the number of shares of Common Stock for which the Common Warrant is exercisable immediately prior to such event. In certain circumstances, the holder will have the right to receive the Black Scholes Value (as defined in the Common Warrant) of the warrant calculated pursuant to a formula set forth in the Common Warrants, payable either in cash or in the same type or form of consideration that was offered and paid to the holders of our Common Stock as described in the Common Warrants.

Transferability

In accordance with its terms and subject to applicable laws, a Common Warrant may be transferred at the option of the holder upon surrender of the Common Warrant to us together with the appropriate instruments of transfer and payment of funds sufficient to pay any transfer taxes (if applicable).

Fractional Shares

No fractional shares of Common Stock will be issued upon the exercise of the Common Warrants. Rather, the number of shares of Common Stock to be issued will, at our election, either be rounded up to the nearest whole number or we will pay a cash adjustment in respect of such final fraction in an amount equal to such fraction multiplied by the exercise price.

Trading Market

There is no established trading market for the Common Warrants, and we do not expect a market to develop. We do not intend to apply for a listing for the Common Warrants on any securities exchange or other nationally recognized trading system. Without an active trading market, the liquidity of the Common Warrant will be limited.

Rights as a Shareholder

Except as otherwise provided in the Common Warrants or by virtue of the holders' ownership of shares of Common Stock, the holders of Common Warrants do not have the rights or privileges of holders of our shares of Common Stock, including any voting rights, until such Common Warrant holders exercise their warrants.

Pre-Funded Warrants

Duration and Exercise Price

Each Pre-Funded Warrant has an initial exercise price per share equal to $0.0001.The Pre-Funded Warrants are immediately exercisable and will expire when exercised in full. The exercise price and number of shares of Common Stock issuable upon exercise is subject to appropriate adjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting our Common Stock and the exercise price.

Exercisability

The Pre-Funded Warrants will be exercisable, at the option of the holder, in whole or in part, by delivering to us a duly executed exercise notice accompanied by payment in full for the number of shares of our Common Stock purchased upon such exercise (except in the case of a cashless exercise as discussed below). The holder (together with its affiliates) may not exercise any portion of such holder's Pre-Funded Warrant to the extent that the holder

would own more than 4.99% (or at the election of the holder, 9.99%) of the outstanding shares of Common Stock immediately after exercise, except that upon at least 61 days' prior notice from the holder to us, the holder may increase the amount of ownership of outstanding shares of Common Stock after exercising the holder's Pre-Funded Warrant up to 9.99% of the number of shares of Common Stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the Pre-Funded Warrant. No fractional shares of Common Stock will be issued in connection with the exercise of a Pre-Funded Warrant. In lieu of fractional shares, we will either pay the holder an amount in cash equal to the fractional amount multiplied by the exercise price or round up to the next whole share.

Cashless Exercise

In lieu of making the cash payment otherwise contemplated to be made to us upon such exercise in payment of the aggregate exercise price, the holder may elect instead to receive upon such exercise (either in whole or in part) the net number of shares of Common Stock determined according to a formula set forth in the Pre-Funded Warrants.

Fundamental Transactions

In the event of any fundamental transaction, as described in the Pre-Funded Warrants and generally including any merger with or into another entity, sale of all or substantially all of our assets, tender offer or exchange offer, or reclassification of our shares of Common Stock, then upon any subsequent exercise of a Pre-Funded Warrant, the holder will have the right to receive as alternative consideration, for each share of Common Stock that would have been issuable upon such exercise immediately prior to the occurrence of such fundamental transaction, the number of shares of Common Stock of the successor or acquiring corporation or of our Company, if it is the surviving corporation, and any additional consideration receivable upon or as a result of such transaction by a holder of the number of shares of Common Stock for which the Pre-Funded Warrant is exercisable immediately prior to such event.

Transferability

Subject to applicable laws, a Pre-Funded Warrant may be transferred at the option of the holder upon surrender of the Pre-Funded Warrant to us together with the appropriate instruments of transfer and payment of funds sufficient to pay any transfer taxes (if applicable).

Exchange Listing

There is no established trading market for the Pre-Funded Warrants. We do not intend to list the Pre-Funded Warrants on any securities exchange or nationally recognized trading system.

Right as a Shareholder

Except as otherwise provided in the Pre-Funded Warrants or by virtue of such holder's ownership of shares of our Common Stock, the holder of the Pre-Funded Warrants do not have the rights or privileges of holders of our Common Stock, including any voting rights, until such Pre-Funded Warrants holder exercise their Pre-Funded Warrants.

Placement Agent Warrants

The Placement Agent Warrants have substantially the same terms as the Common Warrants except with an exercise price of $1.075 and an expiration date of January 25, 2028.

Anti-Takeover Effects of Certain Provisions of Delaware Law, Our Amended and Restated Certificate of Incorporation and Our Amended and Restated Bylaws

Certain provisions of Delaware law and certain provisions that are included in our amended and restated certificate of incorporation and amended and restated bylaws summarized below may be deemed to have an anti-takeover effect and may delay, deter, or prevent a tender offer or takeover attempt that a stockholder might consider to be in its best interests, including attempts that might result in a premium being paid over the market price for the shares held by stockholders. Certain provisions of the charter require the affirmative approval of two-thirds vote of the outstanding stock of the Company.

Preferred Stock

Our amended and restated certificate of incorporation contains provisions that permit our board of directors to issue, without any further vote or action by the stockholders, shares of preferred stock in one or more series and, with respect to each such series, to fix the number of shares constituting the series and the designation of the series, the voting rights (if any) of the shares of the series, and the powers, preferences or relative, participation, optional and other special rights, if any, and any qualifications, limitations or restrictions, of the shares of such series. The issuance of preferred stock could adversely affect the voting power of holders of Common Stock and the likelihood that such holders will receive dividend payments and payments upon liquidation. In addition, the issuance of preferred stock could have the effect of delaying, deferring or preventing change in our control or other corporate action.

Classified board of directors

Our amended and restated certificate of incorporation provides that our board of directors is divided into three classes, designated Class I, Class II, and Class III. Each class has an equal number of directors, as nearly as possible, consisting of one-third of the total number of directors constituting our entire board of directors. The term the initial Class I directors shall terminate on the date of the 2021 annual meeting, the term of the initial Class II directors shall terminate on the date of the 2022 annual meeting, and the term of the initial Class III directors shall terminate on the date of the 2023 annual meeting. At each annual meeting of stockholders beginning in 2021, successors to the class of directors whose term expires at that annual meeting will be elected for a three-year term.

Removal of Directors

Our amended and restated certificate of incorporation provides that stockholders may only remove a director for cause by a vote of no less than a majority of the shares present in person or by proxy at the meeting and entitled to vote.

Director Vacancies

Our amended and restated certificate of incorporation authorizes only our board of directors to fill vacant directorships.

No Cumulative Voting

Our amended and restated certificate of incorporation provides that stockholders do not have the right to cumulate votes in the election of directors.

Special Meetings of Stockholders

Our amended and restated certificate of incorporation and amended and restated bylaws provide that, except as otherwise required by law, special meetings of the stockholders may be called only by an officer at the request of a majority of our board of directors, by the chairperson or president of our board of directors, or by our Chief Executive Officer.

Advance Notice Procedures for Director Nominations

Our amended and restated bylaws provide that stockholders seeking to nominate candidates for election as directors at an annual or special meeting of stockholders must provide timely notice thereof in writing. To be timely, a stockholder's notice generally will have to be delivered to and received at our principal executive offices before notice of the meeting is issued by the secretary of the company, with such notice being served not less than 90 nor more than 120 days before the meeting. Although the amended and restated bylaws do not give our board of directors the power to approve or disapprove stockholder nominations of candidates to be elected at an annual meeting, the amended and restated bylaws may have the effect of precluding the conduct of certain business at a meeting if the proper procedures are not followed or may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect its own slate of directors or otherwise attempting to obtain control of the company.

Action by Written Consent

Our amended and restated certificate of incorporation and amended and restated bylaws provide that any action to be taken by the stockholders must be effected at a duly called annual or special meeting of stockholders and may not be effected by written consent.

Amending our Certificate of Incorporation and Bylaws

Our amended and restated certificate of incorporation may be amended or altered in any manner provided by the DGCL. Certain provisions of our amended and restated certificate of incorporation may only be amended or altered in any manner by the affirmative vote of 66 2/3% of the then-outstanding Common Stock. Our amended and restated bylaws may not be amended by stockholders. Additionally, our amended and restated certificate of incorporation provides that our bylaws may be amended, altered, or repealed by our board of directors.

Authorized but Unissued Shares

Our authorized but unissued shares of Common Stock and preferred stock are available for future issuances without stockholder approval, except as required by the listing standards of Nasdaq, and could be utilized for a variety of corporate purposes, including future offerings to raise additional capital, acquisitions and employee benefit plans. The existence of authorized but unissued and unreserved Common Stock and preferred stock could render more difficult or discourage an attempt to obtain control of the company by means of a proxy contest, tender offer, merger or otherwise.

Exclusive Forum

Our amended and restated certificate of incorporation provides that, unless we consent to the selection of an alternative forum, the Court of Chancery of the State of Delaware shall be the sole and exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a claim of breach of fiduciary duty, any action asserting a claim arising pursuant to the DGCL, any action regarding our amended and restated certificate of incorporation or our amended and restated bylaws or any action asserting a claim against us that is governed by the internal affairs doctrine. Our amended and restated certificate of incorporation further provides that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. 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 our behalf does not apply to suits seeking to enforce a duty or liability created by the Securities Act or Exchange Act. See "Risk Factors — Risks Related to Our Operations — *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.*"

Business Combinations with Interested Stockholders

Subject to certain exceptions, Section 203 of the DGCL prohibits a public Delaware corporation from engaging in a business combination (as defined in such section) with an "interested stockholder" (defined generally as any person who beneficially owns 15% or more of the outstanding voting stock of such corporation or any person affiliated with such person) for a period of three years following the time that such stockholder became an interested stockholder, unless (i) prior to such time the board of directors of such corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder; (ii) upon consummation of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of such corporation at the time the transaction commenced (excluding for purposes of determining the voting stock of such corporation outstanding (but not the outstanding voting stock owned by the interested stockholder) those shares owned (A) by persons who are directors and also officers of such corporation and (B) by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer); or (iii) at or subsequent to such time the business combination is approved by the board of directors of such corporation and authorized at a meeting of stockholders (and not by written consent) by the affirmative vote of at least 66 2/3% of the outstanding voting stock of such corporation not owned by the interested stockholder.

Our amended and restated certificate of incorporation and our amended and restated bylaws provide that we must indemnify our directors and officers to the fullest extent authorized by the DGCL. We are expressly authorized to carry, and we do carry, directors' and officers' insurance providing coverage for our directors, officers and certain employees for some liabilities. We believe that these indemnification provisions and insurance are useful to attract and retain qualified directors and executive directors.

The limitation on 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 duty. These provisions may also have the effect of reducing the likelihood of derivative litigation against directors and officers, even though such an action, if successful, might otherwise benefit us and our stockholders. In addition, your investment may be adversely affected to the extent we pay the costs of settlement and damage awards against directors and officers pursuant to these indemnification provisions.

Listing

Our Common Stock is listed the Nasdaq Capital Market under the symbol "IKT."

Transfer Agent and Registrar

The transfer agent and registrar for our Common Stock is American Stock Transfer & Trust Company. The transfer agent and registrar's address is 6201 15th Ave, Brooklyn, NY 11219.

LEGAL MATTERS

The validity of the issuance of our Common Stock offered in this prospectus will be passed upon for us by McDermott Will & Emery LLP, New York, New York.

EXPERTS

CohnReznick LLP, independent registered public accounting firm, has audited our financial statements at December 31, 2022 and 2021, as set forth in their report. We have included our financial statements in the prospectus and elsewhere in the registration statement in reliance on CohnReznick LLP's report, given on their authority as experts in accounting and auditing.

WHERE YOU CAN FIND ADDITIONAL INFORMATION; INCORPORATION BY REFERENCE

Available Information

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the shares of our Common Stock offered by this prospectus. This prospectus, which constitutes a part of the registration statement, does not contain all of the information set forth in the registration statement, as permitted by the rules and regulations of the SEC. For further information with respect to us and our Common Stock, we refer you to the registration statement, including the exhibits filed as a part of the registration statement. Statements contained in this prospectus concerning the contents of any contract or any other document are not necessarily complete. If a contract or document has been filed as an exhibit to the registration statement, please see the copy of the contract or document that has been filed. Each statement in this prospectus relating to a contract or document filed as an exhibit is qualified in all respects by the filed exhibit. The SEC also maintains an Internet website that contains the registration statement of which this prospectus forms a part, as well as the exhibits thereto. These documents, along with future reports, proxy statements and other information about us, are available at the SEC's website, www.sec.gov.

We are subject to the information and reporting requirements of the Exchange Act, and, in accordance with this law, file periodic reports and other information with the SEC. These periodic reports and other information are available at the SEC's website, www.sec.gov. We also maintain a website at www.inhibikase.com. You may access these materials free of charge as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. Information contained on our website is not a part of this prospectus, and the inclusion of our website address in this prospectus is an inactive textual reference only.

Incorporation by Reference

The SECs rules allow us to incorporate by reference information into this prospectus, which means that we can disclose important information to you by referring you to another document filed separately with the SEC. The information incorporated by reference is deemed to be part of this prospectus, and subsequent information that we file with the SEC will automatically update and supersede that information. Any statement contained in this prospectus or a previously filed document incorporated by reference will be deemed to be modified or superseded for purposes of this prospectus to the extent that a statement contained in this prospectus or a subsequently filed document incorporated by reference modifies or replaces that statement.

This prospectus and any accompanying prospectus supplement incorporate by reference our Annual Report on Form 10-K for the year ended December 31, 2022, filed with the SEC on March 31, 2023.

Notwithstanding the foregoing, information furnished under Items 2.02 and 7.01 of any Current Report on Form 8-K, including the related exhibits under Item 9.01, is not incorporated by reference in this prospectus or any prospectus supplement.

All reports and other documents we subsequently file pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act prior to the termination of this offering, including all such documents we may file with the SEC after the date of the initial registration statement of which this prospectus forms a part and prior to the effectiveness of the registration statement, but excluding any information furnished to, rather than filed with, the SEC, will also be incorporated by reference into this prospectus and deemed to be part of this prospectus from the date of the filing of such reports and documents.

We will provide to each person, upon written or oral request, including any beneficial owners, to whom a prospectus is delivered, a copy of any or all of the reports or documents that have been incorporated by reference in this prospectus, but not delivered with the prospectus. You may obtain any of the documents incorporated by reference in this prospectus from the SEC through the SEC's website at the address provided above. You also may request a copy of any document incorporated by reference in this prospectus (excluding any exhibits to those documents, unless the exhibit is specifically incorporated by reference in this document), at no cost, by writing or telephoning us at the following address and phone number:

Inhibikase Therapeutics, Inc.
3350 Riverwood Parkway SE, Suite 1900
Atlanta, GA 30339
(678) 392-3419

GLOSSARY

ACA	Affordable Care Act
AD	Alzheimer's disease
ADME	absorption, distribution, metabolism and elimination
AMP	average manufacturer price
ANDA	Abbreviated New Drug Application
ASC	Accounting Standards Codification
ASU	Accounting Standards Updates
AUC	area under the curve
BBB	bloodbrain barrier
BLA	Biologics License Application
c-Abl	Abelson protein kinase
CARES	Coronavirus Aid, Relief, and Economic Security Act
cGCPs	current Good Clinical Practices
cGMPs	current Good Manufacturing Practices
Cmax	measured maximum concentration
CML	chronic myelogenous leukemia
CMO	contract manufacturing organization
CMS	Centers for Medicare & Medicaid Services
CNS	central nervous system
CRO	contract research organization
CTA	Clinical Trial Application
DCCA	Defense Contract Audit Agency
DGCL	General Corporation Law of the State of Delaware
DLB	dementia with Lewy body
DOD	Department of Defense
EEA	European Economic Area
EMA	European Medicines Agency
FASB	Financial Accounting Standards Board
FATCA	Foreign Account Tax Compliance Act
FCPA	Foreign Corrupt Practices Act
FDA	U.S. Food and Drug Administration
FDASIA	Food and Drug Administration Safety and Innovation Act
FDCA	U.S. Food, Drug & Cosmetic Act
FINRA	Financial Industry Regulatory Authority
FSMA	Financial Services and Markets Act
GAAP	generally accepted accounting principles
GI	gastrointestinal
HIPAA	Health Insurance Portability and Accountability Act
HITECH	Health Information Technology for Economic and Clinical Health Act
IkT	Inhibikase Therapeutics, Inc.

IMM	irreversible morbidity or mortality
IND	Investigational New Drug Application
IPO	initial public offering
IRB	Institutional Review Board
JCV	John Cunningham Virus
JOBS	Jumpstart Our Business Startups Act
LBs	Lewy bodies
MAA	Marketing Authorization Application
MCMs	medical countermeasures
MMA	Medicare Prescription Drug, Improvement, and Modernization Act
MSA	multiple system atrophy
NDA	New Drug Application
NOAEL	No observed adverse event level
PCAOB	Public Company Accounting Oversight Board
PD	Parkinson's disease
PML	progressive multifocal leukoencephalopathy
PPP	Payroll Protection Program
RAMP™	Re-engineering Approach with Metabolism Preserved
REMS	Risk Evaluation and Mitigation Strategy
RNPV	risk adjusted net present value
SBA	U.S. Small Business Administration
SEC	Securities and Exchange Commission
SHOP	Small Business Health Options Program
SOX	Sarbanes Oxley Act
TCJA	Tax Cuts and Jobs Act
UPDRS	Universal Parkinson's Disease Rating Scale
USPTO	U.S. Patent and Trademark Office
USRPHC	U.S. real property holding corporation
USRPI	U.S. real property interest

INDEX TO FINANCIAL STATEMENTS

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, 2022 and 2021, 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, 2022 and 2021 and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

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 31, 2023

Inhibikase Therapeutics, Inc.
Consolidated Balance Sheets

	December 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 7,188,553	$ 40,750,133
Marketable securities	15,861,620	—
Accounts receivable	39,881	110,141
Prepaid research and development	1,117,616	107,000
Prepaid expenses and other current assets	163,452	1,502,725
Total current assets	24,371,122	42,469,999
Equipment and improvements, net	236,532	—
Right-of-use asset	328,643	—
Total assets	$ 24,936,297	$ 42,469,999
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 1,151,173	$ 1,089,778
Lease obligation, current	145,836	—
Accrued expenses and other current liabilities	2,398,436	2,715,761
Notes payable	—	248,911
Total current liabilities	3,695,445	4,054,450
Lease obligations, net of current portion	205,451	—
Total liabilities	3,900,896	4,054,450
Commitments and contingencies (see Note 14)		
Stockholders' equity:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized at December 31, 2022 and 2021; 0 shares issued and outstanding at December 31, 2022 and 2021	—	—
Common stock, $0.001 par value; 100,000,000 shares authorized; 25,227,051 and 25,155,198 shares issued and outstanding at December 31, 2022 and 2021	25,227	25,155
Additional paid-in capital	68,777,298	68,208,081
Accumulated other comprehensive income	104,718	—
Accumulated deficit	(47,871,842)	(29,817,687)
Total stockholders' equity	21,035,401	38,415,549
Total liabilities and stockholders' equity	$ 24,936,297	$ 42,469,999

See accompanying notes to consolidated financial statements.

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

	Year ended December 31,	
	2022	2021
Revenue:		
Grant revenue	$ 123,440	$ 3,100,605
Total revenue	123,440	3,100,605
Costs and expenses:		
Research and development	12,034,985	11,359,104
Selling, general and administrative	6,217,063	6,507,641
Total costs and expenses	18,252,048	17,866,745
Loss from operations	(18,128,608)	(14,766,140)
Interest income (expense)	74,453	(19,923)
Net loss	(18,054,155)	(14,786,063)
Other comprehensive income, net of taxes:		
Unrealized gains on marketable securities	104,718	$ —
Comprehensive loss	$ (17,949,437)	$ (14,786,063)
Net loss per share — basic and diluted	$ (0.72)	$ (0.81)
Weighted-average number of common shares — basic and diluted	25,211,726	18,209,198

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	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2020	10,050,849	$ 10,051	$ 24,805,929	$ —	$ (15,031,624)	$ 9,784,356
Stock-based compensation expense	—	—	1,531,876	—	—	1,531,876
Issuance of warrants	—	—	688,784	—	—	688,784
Issuance of common stock	9,000	9	60,382	—	—	60,391
Conversion of notes	95,349	95	753	—	—	848
Issuance of initial public offering common stock	15,000,000	15,000	41,120,357	—	—	41,135,357
Net loss	—	—	—	—	(14,786,063)	(14,786,063)
Balance at December 31, 2021	25,155,198	25,155	68,208,081	—	(29,817,687)	38,415,549
Stock-based compensation expense	—	—	458,147	—	—	458,147
Issuance of common stock	50,000	50	66,950	—	—	67,000
Issuance of common stock, stock options exercised	21,853	22	44,120	—	—	44,142
Other comprehensive income	—	—	—	104,718	—	104,718
Net loss	—	—	—	—	(18,054,155)	(18,054,155)
Balance at December 31, 2022	25,227,051	$ 25,227	$ 68,777,298	$ 104,718	$ (47,871,842)	$ 21,035,401

See accompanying notes to consolidated financial statements.

Inhibikase Therapeutics, Inc.
Consolidated Statements of Cash Flows

	Year ended December 31,	
	2022	2021
Operating activities		
Net loss	$ (18,054,155)	$ (14,786,063)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	6,723	—
Stock-based compensation expense	458,147	1,531,876
Non-cash consulting fees	67,000	60,391
Non-cash PPP loan forgiveness	—	(27,550)
Warrant expense	—	688,784
Changes in operating assets and liabilities:		
Accounts receivable	70,258	(110,141)
Operating lease right-of-use assets	38,055	—
Prepaid expenses and other assets	1,339,273	(1,447,888)
Prepaid research and development	(1,010,616)	667,356
Accounts payable	61,395	(630,902)
Operating lease liabilities	(9,859)	
Accrued expenses and other current liabilities	(317,324)	2,082,827
Deferred revenue	—	(2,325,741)
Net cash used in operating activities	(17,351,103)	(14,297,051)
Investing activities		
Purchases of investments — marketable securities	(20,725,462)	—
Maturities of investments — marketable securities	4,963,009	—
Purchases of equipment and improvements	(243,255)	—
Net cash used in investing activities	(16,005,708)	—
Financing activities		
Issuance of common stock from exercise of stock options	44,142	78,500
Payment of employee taxes in connection with stock option exercise	—	(77,652)
Proceeds from issuance of common stock from public offerings, net of issuance costs	—	41,135,357
Repayments of note payable	(248,911)	(42,534)
Net cash (used in)/provided by financing activities	(204,769)	41,093,671
Net (decrease)/increase in cash and cash equivalents	(33,561,580)	26,796,620
Cash and cash equivalents at beginning of year	40,750,133	13,953,513
Cash and cash equivalents at end of year	$ 7,188,553	$ 40,750,133
Supplemental disclosures of cash flow information		
Cash paid for interest	$ 973	$ 1,148
PPP loan forgiveness	$ —	$ 27,550
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 IkT-148009, c-Abl inhibitor, targets the treatment of Parkinson's disease inside and outside the brain as well as other diseases that arise from Abelson Tyrosine Kinases. In 2021, we commenced clinical development of IkT-148009, which we believe can modify the course of Parkinson's disease including its manifestation in the gastrointestinal tract, or GI. The FDA review of the Phase 1/1b data and the protocol for the Phase 2a three-month dosing study resulted in the FDA agreeing with the Company's view that it was appropriate for the Phase 2a study to begin, prompting the Company to initiate the Phase 2a study, the 201 trial, at the end of May 2022. In October 2022, an IND to expand use of IkT-148009 into the Parkinson's-related disease Multiple System Atrophy, or MSA, was filed with the FDA. On November 7, 2022, following review of the IND for IkT-148009 as a treatment for MSA, the FDA notified the Company that it was placing the IkT-148009 programs for Parkinson's disease and MSA on clinical hold. The FDA lifted the full clinical hold in January 2023 for the Parkinson's programs and in March 2023 on the MSA program, opening the IND for MSA. Twenty of thirty-five planned sites will be open as of March 28, 2023. The 201 in Parkinson's trial will start screening patients for enrollment at 50 mg and 100 mg, with the 200 mg dose added back into the trial following submission of the safety and steady-state pharmacokinetic data of the 200 mg dose that was collected in March 2023. Once this data is submitted, the 200 mg dose will be added to the trial after 15 patients have been randomized to 50 mg, 100 mg or placebo groups. The FDA further requested the measurement of visual acuity and examination of the cornea and lens to complement the analysis of retina, macula and fundus that was already part of the ocular monitoring program in the 201 trial.

The Company is also developing platform technologies for alternate ways to deliver protein kinase inhibitors in patients. Our first example of this technology is IkT-001Pro, a prodrug of the anticancer agent imatinib mesylate, to treat Stable Phase Chronic Myelogenous Leukemia (SP-CML). Pursuant to its IND which was cleared by the FDA in August 2022, IkT-001Pro is being evaluated in a two-part dose finding/dose equivalence study in up to 59 healthy volunteers (the 501 trial). The study is 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 400 mg imatinib, the standard-of-care dose for SP-CML. As of this writing, three of four dose escalation cohorts have completed the trial. Only four mild adverse events have been observed, none of clinical significance for IkT-001Pro. IkT-001Pro has high oral bioavailability and a pharmacokinetic profile of delivered imatinib that closely matches the exposure of imatinib delivered as 400 mg imatinib mesylate. Following the 501 study, Inhibikase will confer with the FDA and seek agreement on the requirements for the NDA process following the proposed approval path for IkT-001Pro under the 505(b)(2) approval pathway. The Company plans to simultaneously pursue a superiority study comparing the selected doses of IkT-001Pro to standard-of-care 400 mg imatinib in SP-CML patients using a novel, two-period-wait-list- crossover-switching study.

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 is planned to be completed in 2023.

Liquidity

The Company has recognized recurring losses. At December 31, 2022, the Company had working capital of $20,675,677, an accumulated deficit of $47,871,842, cash and cash equivalents of $7,188,553, marketable securities of $15,861,620 and accounts payable and accrued expenses of $3,549,609.

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 $8.7 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 and general and administrative expenses related to its product candidate programs. The Company anticipates costs and expenses to increase in the future as the Company continues to develop its product candidates.

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

The Company estimates that its working capital at December 31, 2022 and funds raised from the January 2023 Offering is sufficient to fund its normal operations into the fourth quarter of 2024.

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, 2022 and 2021, 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").

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, 2022 and 2021, 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 $7.19 million and $40.75 million at December 31, 2022 and 2021, 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, 2022 and 2021.

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, aright-of-use asset and a lease liability are recognized. Theright-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.

	Estimated Useful Economic Life
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.

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.

Accounting Standards Issued, Not Yet Adopted

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 is currently evaluating the potential impact that this standard may have on its consolidated financial statements and related disclosures.

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 is currently evaluating the potential impact that this standard may have on its consolidated financial statements and related disclosures.

3. Supplemental Balance Sheet Information

Accrued expenses and other current liabilities consist of the following:

	December 31, 2022	December 31, 2021
Accrued consulting	$ 232,390	$ 210,000
Accrued compensation	459,997	421,734
Accrued research and development	1,696,129	2,077,932
Accrued interest	—	968
Accrued other	9,920	5,127
Total accrued expenses and other current liabilities	$ 2,398,436	$ 2,715,761

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 December 31, 2022:

	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

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

5. Marketable Securities

Marketable securities consisted of the following at December 31, 2022.

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, 2022, the Company held three U.S. Treasury debt securities that were in an unrealized gain position totaling $104,718. There were no marketable securities as of December 31, 2021.

The Company received proceeds of $4.96 million from maturities of marketable securities for the year ended December 31, 2022. The Company did not realize any gains or losses from maturities of marketable securities for the year ended December 31, 2022. There were no marketable securities as of December 31, 2021.

6. Equipment and Improvements

Equipment and Improvements, net	
	December 31, 2022
Furniture and office equipment	$ 72,692
Lab equipment	153,668
IT equipment	16,895
	243,255
Less: accumulated depreciation	6,723
Total	$ 236,532

Depreciation expense for the year ended December 31, 2022 was $6,723. There were no equipment and improvements as of December 31, 2021.

7. Notes Payable

Note Payable to CEO

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

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

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, 2022, a total 5,956,282 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

In March 2021, an accredited investor subscribed for, and the Company issued, 9,000 shares of its stock in exchange for consulting services. The fair value of the stock was $60,391 based upon the closing price of the shares on the date of the transaction. Issuance costs were not material. No additional rights or options were granted to this accredited investor in connection with this issuance.

In May 2021, the Company issued 73,496 shares of its common stock in connection with the exercise of 90,415 non-qualified stock options with a strike price of $0.38 per share. The Company withheld 16,919 shares of its common stock for taxes.

In August 2021, the Company issued 21,853 shares of its common stock in connection with the exercise of non-qualified stock options with a strike price of $2.02 per share.

In connection with the June 2021 Offering, the Company issued and sold 15,000,000 fully paid non-assessable shares of its common stock at a public offering price of $3.00 per share. Proceeds from the June 2021 Offering were $41.1 million after deducting offering costs, underwriting discounts and commissions of approximately $3.9 million. The net proceeds are and will be used as working capital by the Company.

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

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

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 8,650,000 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, 2022 and 2021, the Company granted options with an aggregate fair value of $536,965 and $484,669, 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, 2020	3,596,444	$ 2.27	7.73
Granted	215,898	3.88	—
Exercised	(112,268)	0.70	—
Forfeited	(40,708)	0.38	—
Cancelled	—	—	—
Outstanding at December 31, 2021	3,659,366	2.43	6.99
Granted	869,887	1.00	—
Exercised	(21,854)	2.02	—
Forfeited	(113,030)	1.28	—
Cancelled	—	—	—
Outstanding at December 31, 2022	4,394,369	2.19	6.20
Exercisable at December 31, 2022	3,497,813	2.33	1.64

As of December 31, 2022, the intrinsic value of options outstanding was $0.3 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 2022 and the exercise price of each in the money stock option award.

There were no options to purchase stock that vested upon the achievement of performance conditions at December 31, 2022.

The weighted-average fair values of options granted in the years ended December 31, 2022 and 2021 were $0.64 and $2.24, per share, respectively, and were calculated using the following estimated assumptions:

	Year ended December 31,	
	2022	2021
Weighted-average risk-free interest rate	2.17%	0.59%
Expected dividend yield	0.00%	0.00%
Expected volatility	84.88%	82.22%
Expected terms	4.39 years	3.97 years

The total fair values of stock options that vested during the years ended December 31, 2022 and 2021 were $618,157 and $1,150,320, respectively.

As of December 31, 2022, there was $196,977 of total unrecognized compensation cost related tonon-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 1.64 years as of December 31, 2022.

Restricted Stock Units

During the years ended December 31, 2022 and 2021, 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 andnon-employees:

	Year ended December 31,	
	2022	2021
Research and development	$ 120,671	$ 665,834
Selling, general and administrative	337,476	866,042
Total stock-based compensation expense	$ 458,147	$ 1,531,876

10. ATM Program

On May 16, 2022, the Company entered into an Equity Distribution Agreement (the "Agreement") with Piper Sandler & Co. as sales agent (the "Agent"), pursuant to which the Company may, from time to time, issue and sell shares of its common stock, at an aggregate offering price of up to $9.8 million (the "Shares") through the Agent. Under the terms of the Agreement, the Agent may sell the Shares at market prices by any method that is deemed to be an "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 Equity Distribution Agreement by providing a notice of termination to the Agent in accordance with the terms of the Equity Distribution Agreement.

11. Warrants

Kubera North America, Inc. ("Kubera"), in connection with consulting services, was granted a warrant in October 2018 to purchase 4.9% of our issued and outstanding shares of common stock at the time of issuance of the warrant, or 400,866 shares. Kubera warrants became fully vested on October 27, 2021. The warrant has a term of 7 years, is exercisable at $4.79 per share post reverse split. On June 24, 2020 the Kubera warrant was transferred to Kubera N.A. LLC, an affiliate of Kubera.

On January 1, 2019, the Company issued a seven-year warrant to a service provider to purchase 20,533 shares of the Company's common stock with an exercise price of $4.79 per share. The warrants vested immediately. The Company received legal services, as needed, during 2019 under an unwritten agreement with the service provider. The warrants are classified within stockholders' equity at their fair value and were treated as a standalone instrument. The fair value of the warrant was determined to be $82,141 utilizing the Black-Scholes-Merton option-pricing model at the time of issuance and is recorded in selling, general and administrative expenses for the year ended December 31, 2019.

On March 31, 2020, the Company issued a warrant to purchase up to 26,225 shares of its stock to one of its consultants in exchange for legal services, as needed, during 2020. The warrant contains a strike price of $5.67 per share and has a seven-year contractual term. The warrant is classified within stockholders' deficit at its fair value and was treated as a standalone instrument. The grant date fair value of the warrant was determined to be $101,478 utilizing the Black-Scholes-Merton option-pricing model at the time of issuance and is all included in selling, general and administrative expenses for the year ended December 31, 2020.

On August 25, 2020, the Company granted a fully vested warrant to purchase up to 21,854 shares of its common stock to Flagship Consulting, Inc. in connection with consulting services provided to the Company. The warrant is exercisable at a strike price of $5.90 per share and has a contractual term of seven years. The warrant is classified within stockholders' equity at its fair value as a standalone instrument. The grant date fair value of the warrant was determined to be $87,597 utilizing the Black-Scholes-Merton option-pricing model at the time of issuance and is included in selling, general and administrative expenses for the year ended December 31, 2020.

On August 25, 2020, the Company granted a warrant to purchase up to 150,000 shares of its common stock to Flagship Consulting, Inc. in connection with consulting services to be provided to the Company. The warrant is exercisable at a strike price of $5.90 per share and has a contractual term of seven years. The warrant vests in full and becomes exercisable on the first anniversary of the grant date. The warrant is classified within stockholders' equity at its fair value as a standalone instrument over the vesting period. The aggregate grant date fair value of the warrant was determined to be $601,245 utilizing the Black-Scholes-Merton option-pricing model at the time of issuance and will be included in selling, general and administrative expenses as services are rendered during its 12-month vesting period. Through December 31, 2020, $210,848 is included in selling, general and administrative expense.

On December 28, 2020, the Company issued a ten-year warrant to purchase up to a total of 102,435 shares of the Company's common stock with an exercise price of $10.00 per share to certain 2018 investors in consideration for completing the IPO later than March 2019 (the "Late IPO Warrants"). The warrants vested immediately. The warrants are classified within stockholders' equity at their fair value and were treated as a standalone instrument. The fair value of the warrant was determined to be $685,441 utilizing the Black-Scholes-Merton option-pricing model at the time of issuance. The fair value in the amount of $685,441 is included in selling, general and administrative expenses for the year ended December 31, 2020.

The Company issued and sold to its underwriters warrants to purchase up to 90,000 shares of its common stock and up to 750,000 shares of its common stock in connection with its December 2020 IPO and its June 2021 Offering, respectively. The warrants were sold for an aggregate purchase price of $100 for each set of warrants and have five-year terms. The IPO warrant is exercisable beginning June 20, 2021 at an initial exercise price of $12.50 per share of common stock. The June 2021 Offering warrant is exercisable beginning June 15, 2022 at an initial exercise price of $3.75 per share of common stock.

No warrants were exercised for the year ended December 31, 2022 or 2021.

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,	
	2022	**2021**
Numerator:		
Net loss	$ (18,054,155)	$ (14,786,063)
Denominator:		
Weighted-average number of common shares outstanding — basic and diluted	25,211,726	18,209,198
Net loss per share applicable to common stockholders — basic and diluted	$ (0.72)	$ (0.81)

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,	
	2022	2021
Options to purchase shares of stock	4,394,369	3,596,444
Warrants to purchase shares of stock	1,561,913	1,561,913
Total	5,956,282	5,158,357

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, 2022, 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 $24.5 million of federal net operating losses with no expiration. At December 31, 2022, the Company had state net operating loss carryforwards of approximately $24.4 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 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.

The reconciliation of the U.S. federal statutory rate to the Company's effective tax rate is as follows:

	Year Ended December 31,	
	2022	2021
Tax at statutory rate	21.00%	21.00%
State income taxes	6.17%	4.89%
Stock-based compensation	—	(0.13)%
Other	0.03%	0.02%
Change in valuation allowance	(27.20)%	(25.78)%
Effective tax rate	0.00%	0.00%

The significant components of the Company's deferred tax assets consist of the following at December 31, 2022 and 2021:

	December 31,	
	2022	2021
Deferred tax assets:		
Net operating loss carryforwards	$ 6,890,275	$ 5,202,047
Capitalized research and development	2,854,530	—
Stock-based compensation	2,440,885	2,272,970
Accrued expenses	199,961	—
Total deferred tax assets	12,385,651	7,475,017
Deferred tax asset valuation allowance	(12,385,651)	(7,475,017)
Net deferred tax asset	$ —	$ —

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 $4.9 million and $3.8 million for the years ended December 31, 2022 and 2021, respectively. The increases in 2022 and 2021 are primarily related to each year's taxable loss. The Company has no uncertain tax positions at December 31, 2022 and 2021 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.

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, 2022, the Company capitalized $9.8 million and $2.0 million of domestic and foreign R&D expenses, respectively.

14. Commitments and Contingencies

Impact of the COVID-19 Pandemic on Our Operations

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

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

Although the Company did not experience a material impact on its operations during the year ended December 31, 2022 or December 2021, the Company notes the high level of difficulty in determining the future potential adverse financial impact and other effects of COVID-19 on the Company and its programs, given the rapid and dramatic evolution in the course and impact of the pandemic and the societal and governmental response to it.

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 2.5 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 ASUNo. 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 $328,643 at December 31, 2022. The operating lease obligations totaled $351,287 at December 31, 2022, of which $145,836 is included under current liabilities and $205,451 is included under non-current liabilities. The Company recorded lease expense relating to the Office Lease of $56,114 and short-term payments of $58,756 for the year ended December 31, 2022 and short-term payments of $76,816 for the year ended December 31, 2021 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, 2022, 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, 2022, are presented by calendar year as follows:.

Year	
2023	$145,836
2024	150,095
2025	114,966
Total lease payments	410,897
Less: imputed interest	(59,609)
Present value of operating lease liabilities	$351,288

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, 2022, and 2021, 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

Emory University License Agreements

On June 8, 2010, the Company entered into two license agreements with Emory University, the first for which the Company granted to Emory 393,370 shares of its common stock ("License A"), and the second for which the Company granted to Emory 437,078 shares of its common stock ("License B"). The Company recorded $313,500 which represented the fair value of the shares issued as part of the total consideration to Emory for the licenses. The fair value of the shares was determined to be more reliably measurable than the fair value of the consideration received. In exchange, Emory granted the Company and its affiliates an exclusive worldwide sublicensable right and license to practice under certain patent rights and technology to make, have, develop, promote, market, import, export, distribute, offer for sale, sell and otherwise use the licensed products in the field of use anywhere in the world. Unless sooner terminated as provided elsewhere in the agreement, the License A term is the later of 10 years or until the expiration of the patent rights. License B was terminated in May 2013 under the normal course of business. No shares were forfeited or returned and are still owned by Emory.

The Company is required to pay royalties on net sale of products and processes that are covered by the patent rights licensed under the agreement at a percentage in the low single digits, subject to reductions and offsets in certain circumstances, as well as a royalty on net sales of products that the Company sublicenses ranging from low single digit to low double digit percentages based upon stage of development. The Company is obligated to pay potential total milestone payments of $280,000 based upon achievement of certain stages of development. During the years ended December 31, 2022 and 2021, the Company did not incur any milestone fees.

Sphaera Pharma Pte. Ltd.

On March 2, 2012, the Company 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 the Company. On October 5, 2012, the Company 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, the Company has the exclusive right to commercialize 13 of the 24 linkers detailed in the filed patent applications, collectively, the Company Compounds, including the linker attached to Imatinib that comprises the 001Pro oncology product, 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 the Company abandons the Company Compounds. The Company has notified Sphaera that it does not intend to abandon any of the Company Compounds. The Company currently does not have the right to develop the Sphaera Compounds. Additionally, if either party files an IND for a Company Compound for an oncology indication in humans, the non-filing party is prohibited from developing such Company Compound.

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 is entitled to the following milestone payments upon achievement of specified milestones:

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	$ 5,625,000

No milestones have been achieved and, as such, no milestone payments have been made to Sphaera, and the Company does not consider probable that any milestones will be achieved within the next twelve months. Sphaera is also entitled to royalty payments of a percentage of annual net sales and sublicenses ranging in the mid-single digits.

The prosecution of patents related to the Company Compounds, which includes the prodrug technology, is the responsibility of the Company. The parties did not contemplate the development of IkT-001Pro as a competitor to the generic Imatinib now on the market. As such, we and Sphaera are re-negotiating our financial obligations to ensure furtherance of the product to market.

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 $48,408 and $28,938 for the years ended December 31, 2022 and 2021, respectively.

16. Subsequent Events

Concurrent Registered Direct Offering and Private Placements

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 (the "January 2023 Offering"). The January 2023 Offering consisted of (i) 2,800,789 shares of Common Stock sold at $0.86 per share, (ii) Common Warrants to purchase up to 11,627,908 shares of Common Stock with an exercise price of $0.86, and (iii) Pre-Funded Warrants to purchase up to 8,827,119 shares of Common Stock with an exercise price of $0.86 all issued to Armistice Capital

Master Fund Ltd ("Armistice"). The Common Warrants will expire on January 27, 2028. As part of the January 2023 Offering the company further issued H.C. Wainwright & Co., LLC ("Placement Agent Warrants") to purchase up to 406,977 shares of Common Stock with an exercise price of $1.075 and an expiration date of January 25, 2028. As of March 28, 2023, Armistice has exercised 3,028,398 warrants.

The Company received net proceeds from the January 2023 Offering of approximately $8.7 million. Effective January 25, 2023, the Company terminated the Equity Distribution Agreement by providing a notice of termination to the Agent in accordance with the terms of the Equity Distribution Agreement.

Up to 11,627,908 shares of Common Stock underlying the Common Warrants

Up to 4,883,721 shares of Common Stock underlying the Pre-Funded Warrants

Up to 406,977 shares of Common Stock underlying the Placement Agent Warrants

Inhibikase Therapeutics, Inc.

PROSPECTUS

April 4, 2023