2024 Annual Report

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2024

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
FOR THE TRANSITION PERIOD FROM TO

Commission File Number: 001-39676

INHIBIKASE THERAPEUTICS, INC.

(Exact name of Registrant as specified in its Charter)

Delaware	**26-3407249**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
3350 Riverwood Parkway SE, Suite 1900 Atlanta, GA	**30339**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (678) 392-3419

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.001 par value	IKT	The Nasdaq Stock Market LLC

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

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

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

Indicate by check mark whether the Registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES ☒ NO ☐

Indicate by check mark whether the Registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the Registrant was required to submit such files). YES ☒ NO ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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

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

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

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

The aggregate market value of the common stock, par value $0.001 per share, ("Common Stock") held by non-affiliates of the Registrant, based on the closing price of the shares of Common Stock on The Nasdaq Stock Market on June 28, 2024 (the last business day of the Registrant's most recently completed second fiscal quarter) was $7.7 million. Shares of the Registrant's common stock held by each executive officer, director and holder of 5% or more of the outstanding Common Stock have been excluded in that such persons may be deemed to be affiliates. This calculation does not reflect a determination that certain persons are affiliates of the registrant for other purposes. The number of shares of the Registrant's Common Stock outstanding as of March 20, 2025 was 74,341,540.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive Proxy Statement for its 2025 Annual Meeting of Stockholders, which the registrant intends to file pursuant to Regulation 14A with the Securities and Exchange Commission not later than 120 days after the registrant's fiscal year ended December 31, 2024, are incorporated by reference into Part III of this Annual Report on Form 10-K.

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We own various United States ("U.S.") federal trademark applications and unregistered trademarks, including our company name and logo, that we use in connection with the operation of our business. This Annual Report on Form 10-K (this "Annual Report") includes our trademarks and trade names which are protected under applicable intellectual property laws and are our property. This Annual Report also contains trademarks, trade names and service marks of other companies, which are the property of their respective owners. Solely for convenience, trademarks, trade names and service marks referred to in this Annual Report may appear without the ®, ™ or SM symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent permitted under applicable law, our rights or the right of the applicable licensor to these trademarks, trade names and service marks. We do not intend our use or display of other parties' trademarks, trade names or service marks to imply, and such use or display should not be construed to imply, a relationship with, or endorsement or sponsorship of us by these other parties.

From time to time, we may use our website, our X (formerly known as Twitter) account at https://twitter.com/inhibikase and our LinkedIn account at https://www.linkedin.com/company/inhibikase-therapeutics/ to distribute material information about us and for complying with our disclosure obligations under Regulation FD. Our financial and other material information is routinely posted to and accessible on the Investors section of our website, available at *https://www.inhibikase.com/*. Investors are encouraged to review the Investors section of our website because we may post material information on that site that is not otherwise disseminated by us. Information that is contained in and can be accessed through our website or our social media are not incorporated into, and does not form a part of, this Annual Report.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

All statements included or incorporated by reference in this Annual Report, other than statements or characterizations of historical fact, are forward-looking statements. These forward-looking statements are based on our current expectations, estimates, approximations and projections about our industry and business, management's beliefs, and certain assumptions made by us, all of which are subject to change. Forward-looking statements can often be identified by words such as "anticipates," "expects," "intends," "plans," "predicts," "believes," "seeks," "estimates," "may," "will," "should," "would," "could," "potential," "continue," "ongoing," and similar expressions and variations or negatives of these words. These statements are not guarantees of future performance and are subject to risks, uncertainties and assumptions that are difficult to predict. Therefore, our actual results could differ materially and adversely from those expressed in any forward-looking statements as a result of various factors, some of which are listed under "Risk Factors" in Item 1A of this Annual Report. These forward-looking statements speak only as of the date of this Annual Report. We undertake no obligation to revise or update publicly any forward-looking statement for any reason, except as otherwise required by law. In this Annual Report, unless otherwise indicated, the "Company", "we," "us" or "our" refer to Inhibikase Therapeutics, Inc., a Delaware corporation and its subsidiaries, IKT Securities Corporation, a Massachusetts corporation and CorHepta Pharmaceuticals, Inc., a Delaware corporation.

These forward-looking statements include, among other things, statements about:

- the success, cost and timing of our product development activities and clinical trials, including statements regarding the timing of initiation and completion of studies or trials and related preparatory work, the period during which the results of the trials will become available, and our research and development programs;
- our ability to initiate a Phase 2b trial in PAH;
- our ability to successfully complete any clinical trial;
- our ability to successfully manufacture our product candidates for future clinical trials or for commercial use, if approved;
- our ability to obtain and maintain regulatory approval, if obtained, for any product candidates;
- the success of competing therapies that are or become available;
- our ability to obtain funding for our operations, including funding necessary to complete further development and commercialization of our product candidates;
- the commercialization of our product candidates, if approved;
- future agreements with third parties in connection with the commercialization of our product candidates and any other approved product;
- the size and growth potential of the markets for our product candidates, if approved, and our ability to serve those markets;
- the rate and degree of market acceptance of our product candidates, if approved;
- regulatory developments in the United States and foreign countries;
- our ability to contract with third-party suppliers and manufacturers and their ability to perform adequately;
- our ability to attract and retain key scientific or management personnel;
- the accuracy of our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- the impact of laws and regulations; and our expectations regarding our ability to obtain and maintain intellectual property protection for our product candidates;
- the potential for another pandemic, epidemic or outbreak of an infectious disease to disrupt our business plans, product development activities, ongoing clinical trials, including the timing and enrollment of patients, the health of our employees and the strength of our supply chain; and
- our expectations regarding our ability to obtain and maintain intellectual property protection for our product candidates.

PART I

Item 1. Business.

Company Overview

We are a clinical-stage pharmaceutical company developing therapeutics to modify the course of cardiopulmonary and other diseases including those that arise from aberrant signaling through the Abelson Tyrosine Kinase, and type III receptor tyrosine kinases including platelet derived growth factor receptors and proto-oncogene c-KIT ("c-KIT"). The Company's multi-therapeutic pipeline includes IKT-001, a prodrug of imatinib mesylate, for Pulmonary Arterial Hypertension (PAH). IKT-001 was designed to improve the oral absorption, reduce GI side effects and enhance the safety of active pharmaceutical ingredients. IKT-001 is a prodrug of imatinib, an FDA approved treatment for certain blood and stomach cancers. We plan to seek approval from the FDA for IKT-001 in PAH as an orphan indication. We have completed non-human primate safety studies and a bioequivalence clinical trial in healthy volunteers to determine the doses of IKT-001 that are equivalent to imatinib mesylate and the results are being utilized to set the doses in a Phase 2b trial to determine if IKT-001 could be a disease-modifying treatment for PAH. We have also developed risvodetinib (also known as IkT-148009), a selective inhibitor of the non-receptor Abelson Tyrosine Kinases that targets the treatment of Parkinson's disease inside and outside the brain. In 2021, we commenced clinical development of risvodetinib. In 2023, we initiated the Phase 2 201 trial ("201 Trial") for risvodetinib (IkT-148009) as a treatment for Parkinson's disease and completed that trial on October 6, 2024. In January 2025, we reported results from the 201 Trial and decided to pause further development of risvodetinib as we focus our resources on advancing lead program IKT-001 in PAH. We are considering our strategic options for the risvodetinib program.

IKT-001 and PAH

IKT-001 emerged from the Company's medicinal chemistry program that aimed to develop improvements to drugs that inhibit Abelson Tyrosine Kinase and type III receptor tyrosine kinases. IKT-001, a prodrug of imatinib mesylate, was designed to improve areas of the molecule that might play a role in the gastrointestinal ("GI") side effects commonly observed with oral imatinib mesylate, the current standard of care. A three-part dose finding/dose equivalence study in 66 healthy volunteers (known as "the 501 trial") was completed with IKT-001 in 2023. The study was designed to evaluate the 96-hour single-dose pharmacokinetics of imatinib delivered as IKT-001 and determine the dose relationship between IKT-001 and imatinib mesylate. Based on this study it was determined that bioequivalence was established with a 300 mg dose of IKT-001 to a dose of 230 mg of imatinib mesylate while a 500 mg dose of IKT-001 was established as bioequivalent to a dose of 383 mg of imatinib mesylate. These doses are adequate to cover the target systemically and were similar to the doses of imatinib mesylate used in the Phase 3 IMPRES trial in PAH.

On January 19, 2024, we met with the Food and Drug Administration ("FDA") Hematological Malignancy Review Team ("Review Team") in a Pre-New Drug Application ("pre-NDA"), meeting to discuss our bioequivalence studies of IKT-001 and its path to approval. All questions were addressed and summarized in official meeting minutes issued by the FDA on February 12, 2024. During the meeting, we inquired whether additional clinical studies would be needed to seek approval and discussed manufacturing and quality control requirements for approval. The Review Team acknowledged that the 505(b)(2) pathway appeared to be the appropriate pathway for approval of IKT-001. The Review Team also discussed the possible difference between IKT-001 and imatinib mesylate absorption in the gut and recommended that we evaluate whether IKT-001 and imatinib mesylate behave differently with respect to certain gut transporters that regulate absorption. This evaluation was completed and determined that IKT-001 and imatinib mesylate have similar behavior toward the transporters P-glycoprotein ("PGP") and the Breast Cancer Resistance Protein ("BCRP"). Finally, a number of recommendations were discussed to prevent the potential mix-up between IKT-001 and imatinib mesylate either at the pharmacy or by patients for two drugs delivering the same active ingredient. The Company discussed alternate dosage forms for IKT-001 relative to imatinib mesylate as the primary mitigation strategy and will provide a justification of the dosage forms chosen and why they are unlikely to cause medication errors if/when the Company submits a New Drug Application ("NDA") for approval of IKT-001 in these cancer indications.

PAH is a rare disease of the pulmonary microvasculature found in 15 to 50 persons per million within the United States and Europe. The global PAH market size was valued at $7.66 billion in 2023 and is estimated to grow at a compound annual growth rate of 5.4% between 2024 to 2030. Most of the treatments that constitute the standard of care (e.g. ERAs, PDE5s, prostacyclins) primarily act as vasodilators. In 2024, sotatercept was approved for the treatment of PAH on top of SOC. Sotatercept is recombinant fusion protein that acts as a trap for transforming growth factor-beta superfamily ligands, including activin A and bone morphogenetic protein 9. These ligands may play a role in the development and progression of PAH by promoting cell proliferation and fibrosis.

The success of sotatercept has created renewed enthusiasm around the anti-proliferative pathways in PAH. As previously mentioned, imatinib inhibits Abelson Tyrosine Kinase and type III receptor tyrosine kinases and through these pathways inhibits Platelet-derived growth factor receptor which is involved in cell proliferation and angiogenesis as well as Stem cell factor receptor which targets mast cells and other hematopoietic progenitors. Through these targets imatinib may inhibit vascular smooth muscle cell proliferation and fibrosis. This pathway may provide an alternate pathway for disease modification in PAH.

The first reports of the use of imatinib in PAH were published in 2005 and 2006. A phase 2, RCT was subsequently conducted showing clinical benefit of imatinib in PAH. In 2013, the outcome of a Phase 3 trial (IMPRES) evaluating imatinib mesylate as a treatment for PAH was reported, demonstrating that imatinib may improve key parameters associated with PAH. In this study imatinib improved exercise capacity and hemodynamics in patients with advanced PAH but approval was precluded because of the bleeding risk associated with concomitant anti-coagulant therapy and the high discontinuation rate in the imatinib group.

As we considered revisiting the use of imatinib in PAH, we recognized that changes in standard-of-care for these patients may have alleviated much of the safety risk previously observed for imatinib in PAH patients. This analysis prompted us to file a pre-IND ("PIND") meeting request to discuss the application of IKT-001 as a potential disease-modifying treatment for PAH. To evaluate this further, members of the Company met with the FDA Division of Cardiology and Nephrology in a PIND meeting to discuss our plan to utilize IKT-001 in a Phase 2b efficacy, safety and tolerability study in PAH. At the meeting, the FDA confirmed that IKT-001 would be viewed as a New Molecular Entity ("NME") and that the appropriate path for approval remained to be the 505(b)(2) statute. This opens up the possibility of IKT-001 being granted NME status and market exclusivity on approval. The FDA requested at the PIND meeting that we conduct a comparative cell-culture based study of the human Ether-a-go-go-related Gene ("hERG") ion channel, a standard cardiovascular safety test performed for any NME for which a new Investigative New Drug Application ("IND") is to be opened. Neither IKT-001 nor imatinib mesylate were found to be inhibitors of hERG. Following completion of this study, the IND was filed with the FDA on August 9, 2024 and we were cleared to initiate a Phase 2b trial on September 9, 2024. On October 21, 2024, we closed a private placement with gross proceeds of approximately $110 million, before deducting placement fees and offering expenses, to support this program. If the warrants issued in such offering are exercised for cash, the total gross proceeds from the financing may be up to $275 million. We intend to use the net proceeds from the private placement to finance the initiation of a Phase 2b trial in PAH and for general corporate purposes. We have had discussions with the FDA regarding Orphan Drug Designation ("ODD") for delivery of imatinib by IKT-001 for PAH and plan to apply for ODD once the required pre-clinical studies are complete.

We currently have commercialization rights to all of our development programs and patent protection in the United States until 2033 for IKT-001 with upcoming patent application filings potentially extending patent protection for certain methods of treatment using IKT-001 until 2045.

Our Portfolio

IKT-001 In PAH

Market and Commercial Opportunity

In non-human primates IKT-001 displayed up to a 3.4-fold higher no-observed-adverse effect level ("NOAEL") relative to imatinib. This suggests that IKT-001 could reduce some side effects common to imatinib therapy. Specifically in PAH, the GI side effects contributed to the high dropout rate of the Phase 3 IMPRES study. We are planning to conduct clinical studies with the goal of eventually gaining FDA approval for the marketing of IKT-001 in the future. 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 as there remains high unmet need in the PAH market. IKT-001, if approved, will compete for market share from other therapies in PAH and could be one of only a few therapies approved that is disease modifying.

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 with deep drug development and cardiovascular experience.

Mark Iwicki succeeds Dr. Milton H. Werner, founder of Inhibikase, as our Chief Executive Officer. Amit Munshi succeeds Roberto Bellini as Chairman of our board of directors and will continue to serve on our board of directors. Both appointments are effective as of February 14, 2025.

Mr. Iwicki has more than 30 years of biopharmaceutical industry experience. He was previously Chief Executive Officer of KALA BIO. Mr. Iwicki currently serves as the Chairs of boards of directors of KALA BIO and Akero Therapeutics and also serves on the boards of directors of Third Harmonic Bio, Q32 Bio and Merus. He previously served as President and Chief Executive Officer of Civitas Therapeutics and Sunovion Pharmaceuticals Inc. He was also President and Chief Executive Officer of Blend Therapeutics, and President and Chief Operating Officer at Sepracor. Earlier in his career, he was Vice President and Business Unit Head at Novartis Pharmaceuticals Corporation and held management positions at Astra Merck Inc. and Merck & Co. He previously served on the board

of Aimmune Therapeutics. Mr. Iwicki holds a B.S. in Business Administration from Ball State University and an M.B.A. from Loyola University.

Mr. Munshi is a 30-year industry veteran who is currently Chief Executive Officer of Orna Therapeutics and former President, Chief Executive Officer and board member of ReNAgade Therapeutics. Previously, Mr. Munshi served as President and CEO of Arena Pharmaceuticals, which was subsequently acquired by Pfizer, Inc. Previously, Mr. Munshi served as Presidents and Chief Executive Officers of Epirus Biopharmaceuticals and Percivia, and prior to that, was a co-founder and served as Chief Business Officer of Kythera Biopharmaceuticals. Earlier in his career, Mr. Munshi held multiple leadership positions at Amgen, including General Manager, Nephrology Europe. Mr. Munshi holds a B.S. in Economics and a B.A. in History from the University of California, Riverside, and an M.B.A. from the Peter F. Drucker School of Management at Claremont Graduate University.

Chris Cabell, M.D., MHS, FACC., – Dr. Cabell is a cardiologist and joins Inhibikase from CorHepta, where he was Chief Executive Officer. Previously, Dr. Cabell was Chief Medical Officer at Arena Pharmaceuticals, Zura Bio, and Emergent Bio Solutions. Dr. Cabell has also served on multiple corporate and scientific advisory boards. Dr. Cabell is board certified in both internal medicine and cardiology. He is an honors graduate of The Pennsylvania State University and Duke University, where he completed his medical degree, residency in Internal Medicine, fellowship in Cardiology, a master's degree in Health Sciences, and served on the faculty for five years. He is also a Fellow of the American College of Cardiology.

John Adams, Ph.D, – Dr. Adams joins Inhibikase from CorHepta where he was co-founder and Chief Scientific Officer. Previously he was Senior Vice President of Discovery Biology at Iambic Therapeutics, Senior Vice President of Translational Science at Reneo Pharmaceuticals, and the Head of Research at Arena Pharmaceuticals. Dr. Adams earned his Ph.D. in Physiological Science at UCLA and his B.S. Biological Sciences from U.C. Santa Barbara.

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 February 2024, we filed an at-the-market ("ATM") prospectus with the U. S. Securities and Exchange Commission (the "SEC").
- In May 2024, we completed a registered direct offering and raised gross proceeds of $4,000,000 through the sale of our Common Stock and Common Stock equivalents and warrants.
- In October 2024, we completed a private placement and raised gross proceeds of $110,000,000 through the sale of our Common Stock, Common Stock equivalents and warrants.
- In January 2025, we reported results from the 201 Trial and decided to pause further development of risvodetinib as we focus our resources on advancing lead program IKT-001.
- In February 2025, we entered into an Agreement and Plan of Merger and Reorganization ("Merger Agreement") and acquired CorHepta Pharmaceuticals, Inc., a Delaware corporation ("CorHepta"), to expand our product pipeline and to strengthen our scientific leadership. Pursuant to the Merger Agreement, we paid consideration for CorHepta of $15.0 million, subject to a customary purchase price adjustment mechanism. We paid the purchase price pursuant to the issuance of an aggregate of 4,979,101 shares of Common Stock to the former stockholders of CorHepta.

Federal Contracts and Grants

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

Since 2009, we have received six grants from the NIH totaling $10,053,365, to support the development of the RAMP™ drug discovery process and the application of the output of RAMP™ to therapeutic indications in neurodegenerative disease and infectious disease. Since 2017, we have received two grants from the NIH totaling $2,286,778, to support the development of the Company's prodrug platform and oncology applications. Since 2021 we received one grant from NIH totaling $385,888 to support our evaluation of Risvodetinib (IkT-148009) in an animal model of MSA. Under these NIH grants, we must disclose to the Federal government the research methods and outcomes of our research endeavors and patent rights and are subject to the government's march-in rights as they relate to intellectual property. As part of our reporting requirement, we must conduct independent audits of expenditures and file the outcomes of these audits with the NIH and the Department of Health and Human Services ("HHS"). 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 ("DoD"), totaling $7,129,614, to develop so-called Medical Counter Measures ("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, we 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 ("DCAA"), and compliance with federal regulations by the Defense Contract Management Agency ("DCMA").

Material Agreements

Sphaera Pharma Pte. Ltd.

On March 2, 2012, we entered into a collaborative research and development agreement ("Sphaera Agreement"), with Sphaera Pharma Pte. Ltd. ("Sphaera"), to collaborate on the development of the prodrug technology to be applied to protein kinase inhibitors for oncology and non-oncology indications. Under the terms of the Sphaera Agreement, each party would retain its preexisting intellectual property, but any intellectual property conceived or reduced to practice under and certain results arising from the Sphaera Agreement would be assigned to us. On October 5, 2012, we and Sphaera amended the Sphaera Agreement to reflect joint patent applications in the U.S. and India by us and Sphaera for a series of novel compounds. While the underlying intellectual property would be jointly owned, we have the exclusive right to commercialize thirteen of the twenty-four linkers detailed in the filed patent applications, collectively ("Company Compounds"), including the linker attached to imatinib that comprises IKT-001 with the remaining nine linkers owned by Sphaera, ("Sphaera Compounds"). Sphaera has the right to develop the Company Compounds for oncology indications but may not commercialize the Company Compounds unless we abandon the Company Compounds. We have notified Sphaera that we do not intend to abandon the Company Compounds. We do not currently have the right to develop the Sphaera Compounds. Additionally, if either party files an IND for a Company Compound that has been abandoned by the other party for an oncology indication in humans, the non-filing party is prohibited from developing such Company Compound. In 2023, Sphaera liquidated and transferred its interests to Pivot Holding LLC, a U.S. entity ("Pivot"). On September 30, 2024, we and Pivot agreed to amend the agreement and for us to pay $500,000 upon signing as well as payment of the following milestones by us. A one-time payment of $4.4 million upon FDA Approval (as described in the Sphaera Agreement) and a single low digit royalty on net sales of an FDA approved drug. The parties agreed that no further FDA Approval milestone payment(s) shall be due to Pivot in the event that we receive additional FDA Approval(s).

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

Other Agreements

Consulting Agreements

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

Clinical Research Organization Agreements

We work with several clinical research organizations for execution of clinical trials includes medical, analytical and pharmacy support services along with clinical research management and data handling according to a statistical analysis plan. Our clinical development team is formed, in part, by two physicians and a clinical research manager employed by Clintrex Research Corporation and under contract to us, who have specialized expertise in clinical trial development and execution for PD 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 ("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 ("Sponsored Research Agreements"). These Agreements allow us to explore the potential utility of our compounds for therapeutic indications we wish to pursue. We have previously entered into Sponsored Research Agreements with Johns Hopkins, University of Massachusetts Medical School -Worcester Campus and Louisiana State University, Shreveport, and Arizona State University, collectively the Institutions. The scope of work of these Sponsored Research Agreements is derived from the associated grants, in which the sponsored project is a subcontract to the main grant in which the Company is the primary party. 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 ("CMOs"), to manufacture and supply our preclinical and clinical materials to be used during the development of our product candidates. We have established relationships with several CMOs, including AgNo Pharmaceuticals, LLC and PepTech Corporation, both in China, and we have contracted for cGMP manufacturing in the United States with STA Pharmaceutical US LLC and STA Pharmaceuticals Co., Ltd., both subsidiaries of WuXi AppTec Co., Ltd., which is based in China. We have contracted solid dosage formulations of IKT-001 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 and executive team have commercial experience and we have conducted a commercial opportunity assessment for our lead product IKT-001 for PAH 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 PAH 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 candidate for treatment of PAH 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. Companies currently marketing products for PAH include large companies with significant financial resources, that include but are not limited to GlaxoSmithKline, Johnson and Johnson, United Therapeutics, Gilead Sciences, and Merck and Co. Companies currently developing products in PAH are both large companies with significant financial resources as wells as smaller companies and include but are not limited to Merck and Co., Apollo Therapeutics, Novartis Pharmaceuticals, Pfizer, Gossamer Bio, and Insmed, Inc.

Intellectual Property

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

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

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

The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In most countries in which we file, the patent term is 20 years from the earliest date of filing a non-provisional patent application. The patent expirations reported below assume the patent is not rendered invalid or unenforceable by legal action and that all required fees are timely paid. In the United States, a patent may be entitled to Patent Term Adjustment for Patent Office delay. Where known, this has been included in the expiration dates described below. Further, in the United States, the patent term of a single patent that covers an FDA-approved drug may also be eligible for patent term extension, which permits patent term restoration as compensation for the patent term lost during the FDA regulatory review process. The Hatch-Waxman Act permits a patent term extension of up to five years beyond the expiration of the patent. The length of the patent term extension is related to the length of time the drug is under regulatory review. Patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent applicable to an approved drug may be extended and the extension can only be obtained for patents covering the approved drug, a method for using it, or a method for manufacturing it. Similar provisions are available in Europe and certain other foreign jurisdictions to extend the term of a patent that covers an approved drug. In the future, if and when our eligible products receive FDA approval, we expect to apply for patent term extensions on patents covering those products. We plan to seek patent term extensions to any of our issued patents in any jurisdiction where these are available; however, there is no guarantee that the applicable authorities, including the FDA in the United States, will agree with our assessment of whether such extensions should be granted, and if granted, the length of such extensions.

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

As of March 12, our patent portfolio included: (i) nine issued patents and three pending patent applications in the United States (ii) eleven issued foreign patents and four pending foreign patent applications, and (iii) a PCT application. Patents issuing from the applications in this portfolio, if granted, will expire between 2033 and 2045, not taking into account any potential patent-term adjustments or extensions that may be available in the future.

Two families of patents and applications covers compositions of matter for IKT-001 and related chemical compounds, as well as methods of using those compositions. One family includes two issued U.S. patents: U.S. Patent No. 9,487,500, which claims a genus of compounds including IKT-001, and U.S. Patent No. 9,907,796, which claims methods of using a genus of compounds, including IKT-001, 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-001, for cancer treatments. The other family includes a pending United States provisional application that covers methods of using IKT-001 to treat PAH.

Three 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 2045, not taking into account any potential patent-term adjustments or extensions that may be available in the future. These families include seven issued U.S. patents and two pending U.S. patent applications. The issued U.S. patents, U.S. Patent No. 9,828,370, U.S. Patent No. 10,118,923, U.S. Patent No. 10,316,031, U.S. Patent No. 10,344,027, U.S. Patent No. 10,906,896, U.S. Patent no. 11,407,747, and U.S. Patent no. 11,725,005, will expire in 2036, not including any potential patent term extensions, and include claims that cover compositions of matter for IkT-148009 and IkT-01427, as well as claims that cover methods of using those compositions to treat certain cancers and certain infectious diseases. These families also include a pending PCT application. Outside the U.S., these families include issued patents in Japan, Australia, and Canada, pending patent applications in Japan, Canada, and Europe. These families are solely owned by us.

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

The patent positions of pharmaceutical companies like ours are generally uncertain and involve complex legal, scientific and factual questions. Our commercial success will also depend in part on not infringing upon the proprietary rights of third parties. It is uncertain whether the issuance of any third-party patent would require us to alter our development or commercial strategies, or our drugs or processes, obtain licenses or cease certain activities. Our breach of any license agreements or our failure to obtain a license to proprietary rights required to develop or commercialize our future products may have a material adverse impact on us. If third parties prepare and file patent applications in the United States that also claim technology to which we have rights, we may have to participate in interference or derivation proceedings in the United States Patent and Trademark Office ("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, ("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 institutional review board ("IRB") at each clinical site before each trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with current Good Clinical Practices ("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 Risk Evaluation and Mitigation Strategy ("REMS"), and the potential requirement to conduct post-approval studies.

Preclinical Studies

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

Clinical Trials

Clinical trials involve the administration of the investigational new drug to human subjects under the supervision of qualified investigators in accordance with cGCP requirements, which include the requirement that all research subjects provide their informed consent in writing for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA. In addition, an IRB at each institution participating in the clinical trial must review and approve the plan for any clinical trial before it initiates at that institution. Information about certain clinical trials must be submitted within specific time frames to the 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 ("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 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 ("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 irreversible morbidity and mortality ("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 an 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 ("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) NDA is an FDA abbreviated drug approval pathway. The pathway was created by the Hatch-Waxman Amendments of 1984, with 505(b)(2) referring to a section of the FDCA. The provisions of 505(b)(2) were created, in part, to help avoid unnecessary duplication of studies already performed on a previously approved ("reference" or "listed") drug; the section gives the FDA express permission to rely on data not developed by the NDA applicant and for which the applicant has not obtained a right of reference. A 505(b)(2) NDA contains full safety and effectiveness reports but allows at least some of the information required for NDA approval, such as safety and efficacy information on the active ingredient, to come from studies not conducted by or for the applicant. The FDA may also require the applicant to perform additional studies or measurements to support the change from the approved product. The FDA may then approve the new product candidate for all or some of the label indications for which the referenced product has been approved, as well as for any indication sought by the Section 505(b)(2) applicant.

Orphan Drug Designation and Exclusivity

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

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

Post-Approval Requirements

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

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

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

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

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending NDAs or supplements to approved NDAs, or suspension or revocation of product approvals;
- product seizure or detention, or refusal to permit the import or export of products; and
- injunctions or the imposition of civil or criminal penalties.

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

From time to time, legislation is drafted, introduced, passed in Congress and signed into law that could significantly change the statutory provisions governing the approval, manufacturing, and marketing of products regulated by the FDA. In addition to new legislation, FDA regulations, guidance, and policies are often revised or reinterpreted by the agency in ways that may significantly affect the manner in which pharmaceutical products are regulated and marketed.

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. A person of entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. Violations are subject to civil and criminal fines and penalties for each violation, plus up to three times the remuneration involved, imprisonment, and exclusion from government healthcare programs;
- 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 the Health Insurance Portability and Accountability Act of 1996 ("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;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH), imposes 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. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions. Even when HIPAA does not apply, according to the Federal Trade Commission (FTC), failing to take appropriate steps to keep consumers' personal information secure constitutes unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act, 15 U.S.C. § 45(a). The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business and the cost of available tools to improve security and reduce vulnerabilities. Individually identifiable health information is considered sensitive data that merits stronger safeguards;
- federal government price reporting laws, which require us to calculate and report complex pricing metrics in an accurate and timely manner to government programs;
- the federal Physician Payments Sunshine Act requirements, under the Patient Protection and Affordable Care Act ("ACA"), which require manufacturers of certain drugs and biologics to track and report to Centers for Medicare & Medicaid Services ("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; 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 payor, 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 local laws requiring the registration of pharmaceutical sales representatives.

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.

When conducting clinical trials in the EU, we must adhere to the provisions of the EU Clinical Trials Regulation (EU) No 536/2014 ("EU CTR"). The EU CTR requires, among other things, that the prior authorization of an ethics committee and the submission and approval of a clinical trial authorization application be obtained in each applicable EU Member State before commencing a clinical trial in that EU Member State. The EU CTR replaced the previous EU Clinical Trials Directive and aims to simplify and streamline the approval of clinical trials in the EU. For example, the EU CTR implements a coordinated procedure for authorization of clinical trials (through a centralized EU portal known as the Clinical Trials Information System) that is similar to the mutual recognition procedure for marketing authorization of medicinal products, and includes obligations on sponsors to publish clinical trial results.

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

- The centralized 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 ("CHMP") of the European Medicines Agency ("EMA") and which is valid throughout the EU. The centralized procedure is mandatory for certain types of products, such as biotechnology medicinal products, orphan medicinal products and medicinal products containing a new active substance indicated for the treatment of HIV/AIDS, cancer, neurodegenerative disorders, diabetes, autoimmune and other immune dysfunctions and viral diseases. The centralized procedure is optional for products containing a new active substance not yet authorized in the EU, 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 EU 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 EU, this national MA can be recognized in another Member State of the EU through the mutual recognition procedure. If the product has not received a national MA in any EU Member State at the time of application, it can be approved simultaneously in various EU 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 EU 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 EU, 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 EU, 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 EU, 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 EU 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 as the authorized orphan product. The period of market exclusivity is extended by two years for orphan 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. In very selected cases, a marketing authorization may be granted to a similar medicinal product for the same indication as an authorized orphan product during the market exclusivity period, such as where there is consent from the marketing authorization holder for the authorized orphan product, inability to supply sufficient quantities of the product, demonstration of "clinical superiority" by a similar medicinal product to the authorized orphan product. Medicinal products designated as orphan products are eligible for incentives made available by the EU and its Member States to support research into, and the development and availability of, orphan products.

All of the aforementioned EU rules are generally applicable in the EEA.

The European Commission introduced legislative proposals in April 2023 that, if implemented, will replace the current regulatory framework in the EU for all medicines (including those for rare diseases and for children). The European Commission has provided the legislative proposals to the European Parliament and the European Council for their review and approval, and, in April 2024, the European Parliament proposed amendments to the legislative proposals. Once the European Commission's legislative proposals are approved (with or without amendment), they will be adopted into EU law

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 CMS, other divisions of the HHS, 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.

There has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. Both the Trump administration and Congress have indicated that they will continue to seek new legislative and executive measures to control drug costs. In addition, other legislative and regulatory changes have been proposed and adopted in the United States since the ACA was enacted:

- The U.S. Budget Control Act of 2011, among other things, included aggregate reductions of Medicare payments to providers of 2% per fiscal year that remain in effect through 2031.

- The U.S. American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.
- The American Rescue Plan Act of 2021 eliminates the statutory Medicaid drug rebate cap, previously set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024. Due to the Statutory Pay-As-You-Go Act of 2010, estimated budget deficit increases resulting from the American Rescue Plan Act of 2021, and subsequent legislation, Medicare payments to providers were further reduced starting in 2025 absent further legislation.
- The IRA also includes several provisions that will impact our business to varying degrees, including provisions that create a $2,000 out-of-pocket cap for Medicare Part D beneficiaries, impose new manufacturer financial liability on all drugs in Medicare Part D, allow the U.S. government to negotiate Medicare Part B and Part D pricing for certain high-cost drugs and biologics without generic or biosimilar competition, require companies to pay rebates to Medicare for drug prices that increase faster than inflation, and delay the rebate rule that would require pass through of pharmacy benefit manager rebates to beneficiaries. Further, under the IRA, orphan drugs are exempted from the Medicare drug price negotiation program, but only if they have one orphan designation and for which the only approved indication is for that disease or condition. If a product receives multiple orphan designations or has multiple approved indications, it may not qualify for the orphan drug exemption. The implementation of the IRA is currently subject to ongoing litigation challenging the constitutionality of the IRA's Medicare drug price negotiation program. The effect of IRA on our business and the healthcare industry in general is not yet known.

Individual states have also been increasingly active in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional health care authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other health care programs. We expect that additional state and federal healthcare reform measures will be adopted in the future, particularly in light of the new presidential administration, any of which could limit the amounts that federal and state governments will pay for healthcare products and services.

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 Biologics License Application ("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 Abbreviated New Drug Application ("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.

Coverage and Reimbursement

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 ("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 ("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 many 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 EU 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. An EU Member State may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. Historically, products launched in the European Union do not follow price structures of the United States and generally prices tend to be significantly lower.

Employees and Human Capital Resources

As of the date of this Annual Report, we had fifteen full-time employees and one part-time employee. None of our employees are represented by a labor union or covered under a collective bargaining agreement.

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

Trademarks

We use Inhibikase Therapeutics, the Inhibikase Therapeutics logo, and other marks to represent us in the United States and other countries. We have applied to federally register our primary trademarks in our primary market, the United States. Three of the four trademark applications that we filed for (INHIBIKASE, IKT (and Design) and RAMP) have issued to registration, and the fourth application (a second application for INHIBIKASE) is allowed and is currently awaiting registration by the United States Patent and Trademark Office. We have applied to register INHIBIKASE in Australia, Canada, the EU, Japan, Switzerland and the UK. Five of the six foreign trademark applications that we filed for have issued to registration, and the sixth application is currently awaiting registration by the Canada Patent and Trademark Office. In sum, other than the three U.S. federal registrations noted above and the registrations in the ex-US territories listed above, we have not secured trademark protection for any of our trademarks or trade names in any of our other geographic markets, and failure to secure those registrations could adversely affect our business.

Available Information

We maintain an internet website at https://www.inhibikase.com/and make available free of charge through our website our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, including exhibits and amendments to those reports filed or furnished pursuant to Sections 13(a) and 15(d) of the Exchange Act of 1934, as amended ("Exchange Act"). We make these reports available through our website as soon as reasonably practicable after we electronically file such reports with, or furnish such reports to, the SEC. You can review our electronically filed reports and other information that we file with the SEC on the SEC's web site at http://www.sec.gov. We also make available, free of charge on our website, the reports filed with the SEC by our executive officers, directors and 10% stockholders pursuant to Section 16 under the Exchange Act as soon as reasonably practicable after copies of those filings are provided to us by those persons. In addition, we regularly use our website to post information regarding our business, product development programs and governance, and we encourage investors to use our website, particularly the information in the section entitled "Investor Relations," as a source of information about us.

The information on our website is not incorporated by reference into this Annual Report on Form 10-K and should not be considered to be a part of this Annual Report on Form 10-K. Our website address is included in this Annual Report on Form 10-K as an inactive technical reference only.

Item 1A. Risk Factors.

Investing in our securities involves a high degree of risk. You should carefully consider the risks described below, as well as the other information in this Annual Report, 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 Annual Report, before deciding whether to invest in our securities. The occurrence of any of the events or developments described below could harm our business, financial condition,

results of operations and growth prospects. In such an event, the market price of our securities could decline, and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations

Summary of Risks Associated with Our Business

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

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

- We are a clinical-stage drug development company with limited resources, a limited operating history and have no products approved for commercial sale, which may make it difficult to evaluate our current business and predict our future success and viability;
- If we are unable to successfully raise additional capital, our future clinical trials and product development could be limited and our long-term viability may be threatened;
- 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;
- 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;
- If we fail to obtain additional financing, we may be unable to complete the development of and, if approved, commercialization of our product candidates;
- 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, cardiopulmonary and oncological diseases;
- Our focus on IKT-001 as a treatment for PAH may not prove successful;
- We currently contract with various research institutions to perform the research and development activities needed to develop our products, and if we ever choose to or need to find alternative research institutions, we may not be able to do so at all or, if we are able to do so, it may be costly and may cause significant delays in the development and commercialization of our products;
- Positive results from early preclinical or clinical studies of our product candidates are not necessarily predictive of the results of later preclinical studies and any current and future clinical trials of our product candidates;
- We have limited experience with conducting clinical trials for novel drug substances and no history of commercializing pharmaceutical products, which may make it difficult to evaluate the prospects for our future viability;
- Our clinical trials may reveal significant adverse events, toxicities or other side effects not seen in our preclinical studies and may result in a safety profile that could inhibit regulatory approval or market acceptance of any of our product candidates;
- We have concentrated much of our research and development efforts on the treatment of neurodegenerative diseases, a field that has seen limited success in drug development;
- We may encounter substantial delays in our current and planned clinical trials, or may not be able to conduct or complete our clinical trials on the timelines we expect, if at all;
- Our current and planned clinical trials may fail to demonstrate substantial evidence of the safety and efficacy of our product candidates, which would prevent, delay or limit the scope of regulatory approval and commercialization;
- Clinical development is a lengthy and expensive process with an uncertain outcome, and failure can occur at any stage of clinical development;
- The manufacture of our product candidates is complex and difficulties may be encountered in production;

- If, in the future, we are unable to establish sales and marketing capabilities or enter into agreements with third parties to sell and market any product candidates we may develop, we may not be successful in commercializing those product candidates if and when they are approved;
- Even if any product candidates we develop receive marketing approval, they may fail to achieve the degree of market acceptance by physicians, patients, healthcare payors, and others in the medical community necessary for commercial success;
- Even if we are able to commercialize any product candidates, such products may become subject to unfavorable pricing regulations, third-party reimbursement practices, or healthcare reform initiatives, which would harm our business;
- The regulatory approval processes of the FDA, EMA and comparable foreign regulatory authorities are lengthy, time consuming, and inherently unpredictable. Regulatory authorities have substantial discretion in the approval process and may refuse to accept an application, may disagree with our regulatory strategy or proposed pathway for approval or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies;
- We expect to depend in whole or in part on collaborations with third parties for the research, development and commercialization of any product candidates we may develop;
- We contract with third parties for the manufacture of materials for our research programs, preclinical studies and current clinical trials and expect to continue to do so for any future clinical trials and for commercialization of any product candidates that we may develop;
- We depend on a small number of third-party suppliers for key raw materials used in the manufacturing processes for our product candidates, and the loss of these third-party suppliers or their inability to supply us with adequate raw materials could harm our business; and
- If we are unable to obtain and maintain patent protection for any product candidates we develop, our competitors could develop and commercialize products or technology similar or identical to ours, and our ability to successfully commercialize any product candidates we may develop, and our technology may be adversely affected.

Risks Related to Our Business, Financial Condition and Capital Requirements

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

We are a clinical stage drug development company that commenced operations in September 2008. We have limited facilities to conduct fundamental research and we have performed our research and development activities by collaboration with contract service providers, and contract manufacturers and by designing and developing research programs in collaboration with university-based experts who work with us to evaluate mechanism(s) of disease for which we have designed and developed product candidates. Our direct research capabilities are very limited. As of the date of this Annual Report, 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 Annual Report, we have not completed clinical trials for any of our product candidates, obtained marketing approval for any product candidates, manufactured a commercial scale product, or arranged for a third-party to do so on our behalf, or conducted sales and marketing activities necessary for successful product commercialization. Given the highly uncertain nature of drug development, we may never initiate or complete clinical trials for any of our product candidates, obtain marketing approval for any product candidates, manufacture a commercial scale product or arrange for a third-party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization.

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

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

We experienced negative operating cash flows since our inception and funded our operations prior to our initial public offering primarily through private, state and federal contracts and grants. In February 2024, we entered into an At The Market Offering Agreement ("ATM Agreement") with H.C. Wainwright & Co., LLC, as sales agent, which was subsequently terminated in December 2024. 315,338 shares of our Common Stock were sold pursuant to the ATM Agreement for an aggregate gross sales price of $849,188. In October 2024, we completed a private placement of an approximately $110 million ("October 2024 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.

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 timing and results of the Phase 2b clinical objectives referenced under the October 2024 Offering and whether holders of Series A-1 Warrants or Series B-1 Warrants elect to exercise those warrants in accordance with their respective terms;
- 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.

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.

Although we assess our banking and customer relationships as we believe necessary or appropriate, 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.

Inadequate funding for the FDA, the SEC and other government agencies, including from government shut downs, or other disruptions to these agencies' operations, could hinder their ability to hire and retain key leadership and other personnel, prevent

new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

Currently, federal agencies in the U.S. are operating under a continuing resolution that is set to expire on September 30, 2025. Without appropriation of additional funding to federal agencies, our business operations related to our product development activities for the U.S. market could be impacted. The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, the ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new product candidates to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

Our business is affected by macroeconomic conditions, including rising inflation, interest rates and supply chain constraints.

Various macroeconomic factors could adversely affect our business and the results of our operations and financial condition, including changes in inflation, interest rates and overall economic conditions and uncertainties such as those resulting from the current and future conditions in the global financial markets. Recent supply chain constraints have led to higher inflation, which if sustained could have a negative impact on our product development and operations. If inflation or other factors were to significantly increase our business costs, our ability to develop our current pipeline and new product candidates may be negatively affected. Interest rates, the liquidity of the credit markets and the volatility of the capital markets could also affect the operation of our business and our ability to raise capital on favorable terms, or at all, in order to fund our operations. Similarly, these macroeconomic factors could affect the ability of our third-party suppliers and manufacturers to manufacture clinical trial materials for our product candidates.

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 $27,519,886 and $19,028,883 for the years ended December 31, 2024 and 2023, respectively. As of December 31, 2024, we had an accumulated deficit of $94,420,611.

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 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, interest rates, fuel prices, foreign currency fluctuations, international tariffs, social, political and economic risks, public health epidemics or pandemics and acts of war or terrorism;
- continue to 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 various offerings. 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 IKT-001 through preclinical development and clinical trials. 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.

We had cash, cash equivalents, and marketable securities of $97,543,528 as of December 31, 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 future epidemics, pandemics 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. For example, in January 2025, we announced that we were pausing further development of Risvodetinib (IkT-148009) in order focus our resources on advancing our lead program IKT-001.

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, cardiopulmonary and oncological 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, cancer and cardiopulmonary diseases. Our product candidates 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.

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 have advanced into later-stage development for certain of our 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, conducting our clinical trials for IKT-001 and Risvodetinib (IkT-148009) and providing general and administrative support for these operations. Our future success is dependent on our ability to

successfully develop, obtain regulatory approval for, and then successfully commercialize our product candidates, and we may fail to do so for many reasons, including the following:

- our product candidates may not successfully complete preclinical studies or begin or complete clinical trials;
- our product candidates may fail to be delivered across the blood brain barrier ("BBB"), and therefore may not be clinically viable for central nervous system ("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; and
- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; if a product candidate obtains regulatory approval, we may be unable to establish sales and marketing capabilities, or successfully market such approved product candidate, to gain market acceptance; and a product candidate may not be accepted as safe and effective by patients, the medical community or governmental third-party payors.

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

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

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

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

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

We may seek approval of our product candidates into FDA's Real-Time Oncology Review ("RTOR") program. This program may not lead to a faster regulatory review or approval process and does not increase the likelihood that our product candidate(s) will receive marketing approval.

While participation in FDA's RTOR program is voluntary, we may decide to submit oncology marketing applications for our product candidates into FDA's RTOR program. Our acceptance into RTOR does not guarantee or influence approval of our application, which is subject to the same statutory and regulatory requirements for approval as applications that are not included in RTOR. Although early approvals have occurred with applications selected for RTOR, this may not be the case for our application even if it is selected for RTOR. If at any time the FDA determines our participation in RTOR, if selected, is no longer appropriate, the FDA may rescind our acceptance and instruct us to follow routine submission procedures for marketing approval.

We have limited experience with conducting clinical trials for novel drug substances and no history of 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 product candidates and conducting our Phase 1 and Phase 2 clinical trials for Risvodetinib (IkT-148009). Our company has completed observational trials measuring biological parameters for specific indications in human patients from human fluids, but we have never completed a clinical development program for a new interventional drug, and we have not commercialized product candidates. Our product development strategy has included attempts to create molecules through RAMP™ that have predictable human safety margins for the target patient population, but we have never proved that our product candidates have this safety margin in clinical studies all the way through drug approval. We have not conducted pivotal clinical studies for any novel drug candidate and it may be years before any such trials is initiated, if at all. We cannot be certain that planned clinical trials will begin or be completed on time, if at all, that our planned development programs would be acceptable to the FDA or other regulatory authorities, or that, if approval is obtained, such product candidates can be successfully commercialized. Clinical trials and commercializing our product candidates will require significant additional financial and management resources, and reliance on third party clinical investigators, contract research organizations ("CROs"), consultants or collaborators. Relying on third party clinical investigators, CROs or collaborators may result in delays that are outside of our control. If our clinical development program, clinical trials or commercialization of our product candidates were to fail, it would have a material adverse effect on our business, prospects, financial condition and results of operations.

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

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

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

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

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

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

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

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

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

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

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

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

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

- inability to generate sufficient preclinical, toxicology, or other in vivo or in vitro data to support the initiation or continuation of clinical trials;
- delays in confirming target engagement, patient selection or other relevant biomarkers to be utilized in preclinical and clinical product candidate development;
- delays in reaching a consensus with regulatory agencies on study design;
- delays in reaching agreement on acceptable terms with prospective 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 future epidemics or pandemics;
- delays in identifying, recruiting and enrolling suitable patients to participate in our clinical trials, and delays caused by patients withdrawing from clinical trials or failing to return for post-treatment follow-up;
- difficulty collaborating with patient groups and investigators;
- failure by our CROs, other third parties, or us to adhere to clinical trial requirements;
- failure to perform in accordance with the FDA's or any other regulatory authority's current good clinical practices, or cGCPs, requirements, or applicable EMA or other regulatory guidelines in other countries;
- occurrence of adverse events associated with a product candidate that are viewed to outweigh its potential benefits;
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols;
- changes in the standard of care on which a clinical development plan was based, which may require new or additional trials;
- the cost of clinical trials of our product candidates being greater than we anticipate;

- clinical trials of our product candidates producing negative or inconclusive results, which may result in our deciding, or regulators requiring us, to conduct additional clinical trials or abandon product development programs; and
- delays in manufacturing, testing, releasing, validating, or importing/exporting sufficient stable quantities of our product candidates for use in clinical trials or the inability to do any of the foregoing.

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

We could also encounter delays if a clinical trial is suspended or terminated by us, by the data safety monitoring board for such trial or by the FDA, EMA or any other regulatory authority, or if the IRBs of the institutions in which such trials are being conducted suspend or terminate the participation of their clinical investigators and sites subject to their review. Such authorities may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA, EMA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product candidate, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. For example, in November 2002, the FDA issued a clinical hold on the Risvodetinib (IkT-148009) 201 program in PD and the use of Risvodetinib (IkT-148009) in MSA. Although the FDA lifted the clinical hold in January 2023, it still delayed our plans. We may be subject to clinical holds for other product candidates in the future and our progress in the development of this program could 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 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 occurrence of future epidemics or pandemics;
- the design of a trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- competing clinical trials for similar therapies or targeting patient populations meeting our patient eligibility criteria;
- clinicians' and patients' perceptions as to the potential advantages and side effects of the product candidate being studied in relation to other available therapies and product candidates;
- our ability to obtain and maintain patient consents;
- pandemics or similar public health crises; 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. While in November 2024, the Company received authorization for its Phase 2 trial (702 trial) for IKT-001 for PAH, in addition to our already commenced Phase 1 and Phase 2 clinical trials and our two-part dose finding/dose equivalence study for IKT-001, we could encounter problems that could halt our planned clinical trials or require us to repeat such clinical trials. If patients participating in our current and planned clinical trials suffer drug-related adverse actions during the course of such clinical trials, if we or the FDA believe that patients are being exposed to unacceptable health risks, or no meaningful benefits are observed from our product candidates, such clinical trials may have to be suspended or terminated. For example, in June 2024, Aerovate Therapeutics developing an inhaled imatinib product candidate for PAH announced topline Phase 2b clinical trial results indicating the trial did not meet its primary endpoint for improvement in pulmonary vascular resistance versus placebo. Suspension, termination or the need to repeat a clinical trial can occur at any stage and could materially harm the future of our business.

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 REMS, which could have a material adverse effect on the labeling, distribution or promotion of a drug product.

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

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

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

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

Many of our current or potential competitors, either alone or with their strategic partners, have significantly greater financial resources and expertise in research and clinical development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals, and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Our commercial opportunities could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient, or are less expensive than any products that we may develop. Furthermore, currently approved products could be discovered to have application for treatment of the same disease indications as our product candidates, which could give such products significant regulatory and market timing advantages over any of our product candidates. Our competitors also may obtain FDA, European Commission 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 or European Commission for indications our product candidates are targeting, which could result in our competitors establishing a strong market exclusivity 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. Furthermore, if any third-party manufacturers with whom we contract fails to perform its obligations, we may be forced to manufacture the materials ourselves, for which we may not have the capabilities or resources, or enter into an agreement with a different third-party manufacturer, which we may not be able to do on reasonable terms, if at all. In either scenario, our clinical trials supply could be delayed significantly as we establish alternative supply sources. In some cases, the technical skills required to manufacture our products or product candidates may be unique or proprietary to the original third-party manufacturer and we may have difficulty, or there may be contractual restrictions prohibiting us from, transferring such skills to a back-up or alternate supplier, or we may be unable to transfer such skills at all. In addition, if we are required to change third-party manufacturers for any reason, we will be required to verify that the new third-party manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations. We will also need to verify, such as through a manufacturing comparability study, that any new manufacturing process will produce our product candidate according to the specifications previously submitted to the FDA or another regulatory authority. The delays associated with the verification of a new third-party manufacturer could negatively affect our ability to develop product candidates or commercialize our products in a timely manner or within budget. Furthermore, a third-party manufacturer may possess technology related to the manufacture of our product candidate that such third-party manufacturer owns independently. This would increase our reliance on such third-party manufacturer or require us to obtain a license from such third-party manufacturer in order to have another third-party manufacturer produce our product candidates. In addition, changes in manufacturers often involve changes in manufacturing procedures and processes, which could require that we conduct bridging studies between our prior clinical supply used in our clinical trials and that of any new manufacturer. We may be unsuccessful in demonstrating the comparability of clinical supplies which could require the conduct of additional clinical trials.

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 third -party manufacturers 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.

Additionally, in 2024, there was Congressional activity related to interactions with Chinese biotech companies, including the introduction of the BIOSECURE Act. Although the BIOSECURE Act was not ultimately passed by Congress, had this bill become law, or if similar laws are passed in the future, they would have the potential to restrict the ability of U.S. biopharmaceutical companies

that purchase services or products from, or otherwise collaborate with, certain Chinese biotechnology companies "of concern" without losing the ability to contract with, or otherwise receive funding from, the U.S. government. If we chose to do business with companies in China, including some named in these bills, it is possible some of our contractual counterparties could be impacted by the legislation described above.

If the third parties that we currently engage, or engage in the future, to supply materials or manufacture products for our preclinical tests and clinical trials should cease to continue to do so for any reason, we would likely experience delays in advancing these tests and trials while we identify and qualify replacement suppliers or manufacturers, and we may be unable to obtain replacement supplies on terms that are favorable to us or at all. In addition, if we are not able to obtain adequate supplies of its product candidates or the substances used to manufacture them, it will be more difficult for us to develop its product candidates and compete effectively.

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

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

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

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

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

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

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

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

- the efficacy and safety of such product candidates as demonstrated in pivotal clinical trials and published in peer-reviewed journals;
- the potential and perceived advantages compared to alternative treatments;
- the ability to offer our products for sale at competitive prices;
- the ability to offer appropriate patient access programs, such as co-pay assistance;
- the extent to which physicians recommend our products to their patients;
- convenience and ease of dosing and administration compared to alternative treatments;
- the clinical indications for which the product candidate is approved by the FDA, European Commission 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 ("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, European Commission 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 ("Hatch-Waxman Act"), a pharmaceutical manufacturer may file an ANDA, seeking approval of a generic copy of an approved, small molecule innovator product. Under the Hatch-Waxman Act, a manufacturer may also submit an NDA under section 505(b)(2) that references the FDA's prior approval of the small molecule innovator product. A 505(b)(2) NDA product may be for a new or improved version of the original innovator product. The Hatch-Waxman Act also provides for certain periods of regulatory exclusivity, which preclude FDA approval (or in some circumstances, FDA filing and reviewing) of an ANDA or 505(b)(2)NDA. These include, subject to certain exceptions, the period during which an FDA-approved drug is subject to orphan drug exclusivity. In addition to the benefits of regulatory exclusivity, an innovator NDA holder may have patents claiming the active ingredient, product formulation or an approved use of the drug, which would be listed with the product in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations," known as the "Orange Book." If there are patents listed in the Orange Book, a generic or 505(b)(2) applicant that seeks to market its product before expiration of the patents must include in the ANDA a "Paragraph IV certification," challenging the validity or enforceability of, or claiming non-infringement of, the listed patent or patents. Notice of the certification must be given to the innovator, too, and if within 45 days of receiving notice the innovators use to protect its patents, approval of the ANDA is stayed for 30 months, or as lengthened or shortened by the court.

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

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

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

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

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

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

Risks Related to Regulatory Approval and Other Legal Compliance Matters

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

The time required to obtain approval by the FDA, European Commission 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. The U.S. Supreme Court's July 2024 decision to overturn prior established case law giving deference to regulatory agencies' interpretations of ambiguous statutory language has introduced uncertainty regarding the extent to which FDA's regulations, policies and decisions may become subject to increasing legal challenges, delays, and/or changes. We have not submitted for, or obtained regulatory approval for any product candidate, and it is possible that none of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval.

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

- the FDA, EMA or comparable foreign regulatory authorities may disagree with the design, implementation or results of our preclinical or clinical trials;

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

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

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

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

On January 19, 2024, our members along with its medical oncology consultants met with the Review Team in a Pre-NDA meeting to discuss our bioequivalence studies of IKT-001 and its path to approval. All questions were addressed and summarized in official meeting minutes issued by the FDA on February 12, 2024. During the meeting we inquired whether additional clinical studies may be needed to seek approval and discussed manufacturing and quality control requirements for approval. The Review Team acknowledged that the 505(b)(2) pathway appears to be the appropriate pathway for approval of IKT-001 and indicated that, pending formal review of our clinical data, clinical studies completed to date indicate that 600 mg and 800 mg IKT-001 provides similar exposures to 400 mg and 600 mg imatinib mesylate, respectively, subject to review of the NDA upon filing. In addition, given that imatinib mesylate is approved for use between 300 mg and 800 mg once daily for a variety of blood and gastrointestinal cancers, the Review Team stated that if we intend to seek approval across all currently approved indications, we should evaluate additional dose(s) as needed to measure the safety, tolerability and bioequivalent dose of IKT-001 that would deliver up to 800 mg, the highest approved dose of imatinib mesylate. We are considering the study of the 1200 mg dose of IKT-001 that is expected to lead to exposures equivalent to 800 mg imatinib. The Review Team also discussed the possible difference between IKT-001 and imatinib mesylate absorption in the gut and recommended that we evaluate whether IKT-001 and imatinib mesylate behave differently with respect to certain gut transporters that regulate absorption. We are in alignment with the FDA and are initiating the necessary pre-clinical test to evaluate this further to ensure that delivery of imatinib by IKT-001 mimics imatinib mesylate in all respects. Finally, a number of recommendations were discussed to prevent the potential mix-up between IKT-001 and imatinib mesylate either at the pharmacy or by patients for two drugs delivering the same active ingredient. We discussed alternate dosage forms for IKT-001 relative to imatinib mesylate as the primary mitigation strategy and will provide a justification of the dosage forms chosen and why they are unlikely to cause medication errors. We will request milestone-based meetings with the Review Team to ensure the Company and the Review Team remain aligned as we complete the necessary preclinical, clinical, manufacturing and quality control requirements for potential

approval, but there is no guarantee that Review Team interactions will ultimately lead to the approval of IKT-001 or any other product candidates we may develop.

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

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

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

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

If we file a Section 505(b)(2) application that relies in whole or in part on studies conducted by a third-party, we will be required to certify to the FDA that either: (1) there is no patent information listed in the FDA's publication *Approved Drug Products with Therapeutic Equivalence Evaluations* ("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.

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 European Commission 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 ("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-001 by the FDA 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-001, 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. Also, the FDA may further reevaluate the Orphan Drug Act and its regulations and policies. We do not know if, when, or how the FDA may change the orphan drug regulations and policies in the future, and it is uncertain how any changes might affect our business. Depending on what changes the FDA may make to its orphan drug regulations and policies, our business could be adversely impacted. If we lose orphan drug designation in the future for IKT-001 the development costs may outweigh the economic benefits from FDA approval, if any, and commercialization.

Similarly, in the EU, the European Commission, upon the recommendation of the EMA's Committee for Orphan Medicinal Products, grants an orphan designation in respect of a product if its sponsor can show that: (1) the product is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition; (2) either (i) such condition affects no more than 5 in 10,000 persons in the EU when the application is made, or (ii) it is unlikely that, without the benefits derived from orphan status, sales of the product in the EU would generate sufficient return in the EU to justify the necessary investment in its development; and (3) there is no satisfactory method of diagnosis, prevention or treatment of such condition authorized for marketing in the EU, or, if such a method exists, the product would be of a significant benefit to those affected by that condition. In the EU, orphan designation entitles a party to financial incentives such as reduction of fees or fee waivers.

Generally, if a product with an orphan designation subsequently receives the first regulatory approval for the indication for which it has such designation in the EU, the product is entitled to a ten year period of marketing exclusivity, which precludes the EMA from approving another marketing authorization application for a similar medicinal product in the same indication for that time period, except in limited circumstances. The EU market exclusivity period can be reduced to six years if, at the end of the fifth year, a product no longer meets the criteria for orphan designation or if the product is sufficiently profitable so that market exclusivity is no longer justified. Proposed amendments to EU regulations regarding orphan medicines are under consideration that, if implemented, could reduce the current ten-year marketing exclusivity period in the EU for certain orphan medicines. Even if we obtain orphan exclusivity for any product candidate, that exclusivity may not effectively protect our product candidate from competition because different products can be approved for the same condition.

If, in the future, we seek a breakthrough therapy designation by the FDA for our product candidates, 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.

In the future, we may seek a breakthrough therapy designation for our 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 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.

In addition, in the EU, we may seek to participate in the PRIority MEdicines ("PRIME") scheme for our potential product candidates. The PRIME scheme is intended to encourage development of products in areas of unmet medical need and provides accelerated assessment of products representing substantial innovation, where the marketing authorization application will be made through the centralized procedure in the EU. Products from small-and medium-sized enterprises may qualify for earlier entry into the PRIME scheme than larger companies on the basis of compelling non-clinical data and tolerability data from initial clinical trials. Eligible products must target conditions for which there is an unmet medical need (no treatment option exists in the EU or the product can offer a major therapeutic advantage over existing treatments). Many benefits accrue to sponsors of product candidates with PRIME

designation, including but not limited to, early and proactive regulatory dialogue with the EMA, frequent discussions on clinical trial designs and other development program elements, and accelerated marketing authorization application assessment once a dossier has been submitted. There is no guarantee, however, that our potential product candidates would be deemed eligible for the PRIME scheme and, even if we do participate in the PRIME scheme, where during the course of development a product no longer meets the eligibility criteria, support under the PRIME scheme may be withdrawn. PRIME eligibility does not change the standards for product approval, and there is no assurance that any such designation or eligibility will result in expedited review or 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.

Other legislative changes have been adopted since the Affordable Care Act was enacted, including aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect in April 2013 and will remain in effect through 2031. Under current legislation, the actual reductions in Medicare payments may vary up to 4%. The Consolidated Appropriations Act (CAA), which was signed into law by President Biden in December 2022, made several changes to sequestration of the Medicare program. Section 1001 of the CAA delays the 4% Statutory Pay-As-You-Go Act of 2010, or "PAYGO" sequester for two years, through the end of calendar year 2024. Triggered by the enactment of the American Rescue Plan Act of 2021, the 4% cut to the Medicare program would have taken effect in January 2023. The CAA's health care offset title includes Section 4163, which extends the 2% Budget Control Act of 2011 Medicare sequester for six months into fiscal year 2032 and lowers the payment reduction percentages in fiscal years 2030 and 2031.

The American Taxpayer Relief Act of 2012 reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Further, with passage of the Inflation Reduction Act (IRA) in August 2022, Congress authorized Medicare beginning in 2026 to negotiate lower prices for certain costly single-source drug and biologic products that do not have competing generics or biosimilars. This provision is limited in terms of the number of pharmaceuticals whose prices can be negotiated in any given year and it only applies to drug products that have been approved for at least 9 years and biologics that have been licensed for 13 years. Drugs and biologics that have been approved for a single rare disease or condition are categorically excluded from price negotiation. In addition, the new legislation provides that if pharmaceutical companies raise prices in Medicare faster than the rate of inflation, they must pay rebates back to the government for the difference. The IRA also caps Medicare out-of-pocket drug costs at an estimated $4,000 a year in 2024 and, thereafter beginning in 2025, at $2,000 a year. The IRA permits the U.S. Department of Health and Human Services or "HHS" to implement many of these provisions through guidance, as opposed to regulation, for the initial years. HHS has and will continue to issue and update guidance as these programs are implemented. On August 15, 2024, HHS announced the agreed-upon prices of the first ten drugs that were subject to price negotiations, which take effect in January 2026. HHS will select up to fifteen additional products covered under Part D for negotiation in 2025. Each year thereafter more Part B and Part D products will become subject to the Medicare Drug Price Negotiation Program. The Medicare Drug Price Negotiation Program is currently subject to legal challenges. The outcome of this litigation as well as the effects of the IRA on the pharmaceutical industry cannot yet be fully determined but is likely to be significant.

We expect that healthcare reform measures 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. Such laws include, without limitation, federal and state anti-kickback, fraud and abuse, false claims, data privacy and security and physician and other healthcare provider payment transparency laws and regulations. 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 ("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;
- federal government price reporting laws, which require us to calculate and report complex pricing metrics in an accurate and timely manner to government programs;
- 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.

Data collection is governed by restrictive regulations governing the use, processing and cross-border transfer of personal information.

Federal and state laws govern the privacy and security of health information in certain circumstances, some of which are more stringent than HIPAA and many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. By way of example, the California Consumer Privacy Act (CCPA) gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing, and receive detailed information about how their personal information is used. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. The CCPA may increase our compliance costs and potential liability. Similar laws have been passed in numerous other states. Although many of the existing state privacy laws exempt clinical trial information and health information governed by HIPAA, future privacy and data protection laws may be broader in scope. The existence of a variety of comprehensive privacy laws in different states would make our compliance obligations more complex and costly and may increase the likelihood that we may be subject to enforcement actions or otherwise incur liability for noncompliance. Moreover, a number of other states have passed or proposed more limited privacy laws that focus on specific privacy issues such as biometric data or the privacy of consumer health information, such as Washington state's My Health My Data Act, which has a private right of action that further increases the relevant compliance risk. Connecticut and Nevada have also passed similar laws regulating consumer health data and a health privacy law is awaiting the governor's signature in New York. At the federal level, the FTC has used its authority over "unfair or deceptive acts or practices" to impose stringent requirements on the collection and disclosure of sensitive categories of personal information, including health information. Moreover, the FTC's expanded interpretation of a "breach" under its Health Breach Notification Rule could impose new disclosure obligations that would apply in the event of a qualifying breach. These various privacy and security laws may impact our business activities, including our identification of research subjects, relationships with business partners and ultimately the marketing and distribution of our products.

Risks Related to Our Reliance on Third Parties

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

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

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

Our CROs are not our employees, and except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our ongoing preclinical programs and any future clinical trials. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the preclinical or clinical data they obtain is compromised due to the failure to adhere to our preclinical or future clinical protocols, regulatory requirements or for other reasons, our preclinical and any future clinical trials may be extended,

delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, the commercial prospects for our product candidates would be harmed, our costs could increase substantially and our ability to generate revenue could be delayed.

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

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

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

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

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

Such collaborations pose the following risks to us:

- collaborators generally have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not properly obtain, maintain, enforce, or defend intellectual property or proprietary rights relating to our product candidates or research programs or may use our proprietary information in such a way as to expose us to potential litigation or other intellectual property related proceedings, including proceedings challenging the scope, ownership, validity and enforceability of our intellectual property;
- we may need the cooperation of our collaborators to enforce or defend any intellectual property we contribute to or that arises out of our collaborations, which may not be provided to us;
- disputes may arise between the collaborators and us that result in the delay or termination of the research, development, or commercialization of our product candidates or research programs or that result in costly litigation or arbitration that diverts management attention and resources;
- collaborators may decide to not pursue development and commercialization of any product candidates we develop or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborator's strategic focus or available funding or external factors such as an acquisition that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials, or require a new formulation of a product candidate for clinical testing;

- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates or research programs if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- collaborators with marketing and distribution rights to one or more product candidates may not commit sufficient resources to the marketing and distribution of such product candidates;
- we may lose certain valuable rights under circumstances identified in our collaborations; collaborators may undergo a change of control and the new owners may decide to take the collaboration in a direction which is not in our best interest;
- collaborators may become bankrupt, which may significantly delay our research or development programs, or may cause us to lose access to valuable technology, know-how or intellectual property of the collaborator relating to our products, product candidates or research programs;
- key personnel at our collaborators may leave, which could negatively impact our ability to productively work with our collaborators; collaborations may require us to incur short- and long-term expenditures or issue securities that dilute our stockholders or disrupt our management and business; collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates; and
- collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all. If a present or future collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our development or commercialization program under such collaboration could be delayed, diminished, or terminated.

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

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

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

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

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

- the possible breach of the manufacturing agreement by the third-party;

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

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

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

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

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

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

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

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

We rely on third-party suppliers for the raw materials required for the production of our product candidates. Our dependence on these third-party suppliers and the challenges we may face in obtaining adequate supplies of raw materials involve several risks, including limited control over pricing, availability, quality and delivery schedules. As a small company, our negotiation leverage is limited and we are likely to get lower priority than our competitors who are larger than we are. We cannot be certain that our suppliers will continue to provide us with the quantities of these raw materials that we require or satisfy our anticipated specifications and quality requirements. Any supply interruption in limited or sole source draw 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. For example, on February 1, 2025, the U.S. imposed a 10% additional tariff on imports from China. Historically, tariffs have led to increased trade and political tensions. In response to tariffs, other countries have implemented retaliatory tariffs on U.S. goods. Political tensions as a result of trade policies could reduce trade volume, investment, technological exchange and other economic activities between major international economies, resulting in a material adverse effect on global economic conditions and the stability of global financial markets. Any changes in political, trade, regulatory, and economic conditions, including U.S. trade policies, could have a material adverse effect on our financial condition or results of operations.

Regulators and legislators in the U.S. are increasingly scrutinizing and restricting certain personal data transfers and transactions involving foreign countries. For example, the Biden Administration's executive order Preventing Access to Americans' Bulk Sensitive Personal Data and United States Government-Related Data by Countries of Concern as implemented by Department of Justice regulations issued in December 2024, prohibits data brokerage transactions involving certain sensitive personal data categories, including health data, genetic data, and biospecimens, to countries of concern, including China. The regulations also restrict certain investment agreements, employment agreements and vendor agreements involving such data and countries of concern, absent specified cybersecurity controls. Actual or alleged violations of these regulations may be punishable by criminal and/or civil sanctions, and may result in exclusion from participation in federal and state programs.

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.

Risks Related to Our Intellectual Property

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

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

patent claims may be insufficient to prevent third parties, such as our competitors, from utilizing our technology. Any failure to obtain or maintain patent protection with respect to our product candidates could have a material adverse effect on our business, financial condition, results of operations, and prospects.

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

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

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

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

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

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

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

result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. Assuming that other

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

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

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

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

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

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

Depending upon the timing, duration and specifics of any FDA marketing approval of any product candidates we may develop, one or more of our owned or in-licensed U.S. patents may be eligible for limited patent term extension under the Hatch-Waxman Act. The Hatch-Waxman Act permits a patent term extension of up to five years as compensation for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended and only those claims covering the approved drug, a method for using it, or a

method for manufacturing it may be extended. Similar extensions as compensation for patent term lost during regulatory review processes are also available in certain foreign countries and territories, such as in Europe under a Supplementary Patent Certificate. However, we may not be granted an extension in the United States and/or foreign countries and territories because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is shorter than what we request, our competitors may obtain approval of competing products following our patent expiration, and could have a material adverse effect on our business, prospects, financial condition and results of operations.

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

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

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

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

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

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

efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive, and time-consuming, and the outcome is unpredictable.

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

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

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

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

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

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

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

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

Numerous U.S. and foreign issued patents and pending patent applications owned by third parties exist relating to the fields in which we are developing our product candidates. As the pharmaceutical industry expands and more patents are issued, the risk increases

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

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

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

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

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

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

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions, or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing, or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or

proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

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

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

Intellectual property rights do not necessarily address all potential threats.

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

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

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

The use of new and evolving technologies, such as artificial intelligence, in our offerings may result in spending material resources and presents risks and challenges that can impact our business including by posing security and other risks to our confidential information, proprietary information and personal information, and as a result we may be exposed to reputational harm and liability.

We continue to build and integrate artificial intelligence into our offerings, and this innovation presents risks and challenges that could affect its adoption, and therefore our business. If we enable or offer solutions that draw controversy due to perceived or actual negative societal impact, we may experience brand or reputational harm, competitive harm or legal liability. The use of certain artificial intelligence technology can give rise to intellectual property risks, including compromises to proprietary intellectual property and intellectual property infringement. Additionally, we expect to see increasing government and supranational regulation related to artificial intelligence use and ethics, which may also significantly increase the burden and cost of research, development and compliance in this area. For example, the EU's Artificial Intelligence Act (AI Act) the world's first comprehensive AI law is anticipated to enter into force in Spring 2024 and, with some exceptions, become effective 24 months thereafter. This legislation imposes significant obligations on providers and deployers of high risk artificial intelligence systems, and encourages providers and deployers of artificial intelligence systems to account for EU ethical principles in their development and use of these systems. If we develop or use AI systems that are governed by the AI Act, it may necessitate ensuring higher standards of data quality, transparency, and human oversight, as well as adhering to specific and potentially burdensome and costly ethical, accountability, and administrative requirements. The rapid evolution of artificial intelligence will require the application of significant resources to design, develop, test and maintain our products and services to help ensure that artificial intelligence is implemented in accordance with applicable law and regulation and in a socially responsible manner and to minimize any real or perceived unintended harmful impacts. Our vendors may in turn incorporate artificial intelligence tools into their own offerings, and the providers of these artificial intelligence tools may not meet existing or rapidly evolving regulatory or industry standards, including with respect to privacy and data security. Further, bad actors around the world use increasingly sophisticated methods, including the use of artificial intelligence, to engage in illegal activities involving the theft and misuse of personal information, confidential information and intellectual property. Any of these effects could damage our reputation, result in the loss of valuable property and information, cause us to breach applicable laws and regulations, and adversely impact our business.

Risks Related to Our Operations

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

As of the date of this Annual Report, we had fifteen full-time employees and one part-time employee. 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.

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 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 stock option grants that vest over time and performance stock if performance conditions are met. In the future we may grant restricted stock units. The value to employees of these equity grants that vest over time may be significantly affected by movements in our stock price that are beyond our control, and may at any time be insufficient to counteract more lucrative offers from other companies. Although we have employment agreements with our key employees, these employment agreements provide for at-will employment, which means that any of our employees could leave our employment at any time, with or without notice. If we are unable to attract and incentivize quality personnel on acceptable terms, or at all, it may cause our business and operating results to suffer.

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

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

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

Despite the implementation of security measures, our internal computer systems and those of our future CROs and other contractors and consultants may be vulnerable to damage from computer viruses and unauthorized access. Although to our knowledge we have not experienced any such material system failure or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed, ongoing or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on our third-party research institution

collaborators for research and development of our product candidates and other third parties for the manufacture of our product candidates and to conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or systems, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of our product candidates could be delayed.

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

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

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

As of December 31, 2024, we had federal net operating loss carryforwards of approximately $1.6 million, which will begin to expire in varying amounts annually beginning in 2030, and $46.5 million of federal net operating losses with no expiration. At December 31, 2024, we had state net operating loss carryforwards of approximately $36.1 million which will begin to expire in varying amounts annually beginning in 2030. These net operating loss carry forwards could expire unused and be unavailable to offset future income tax liabilities. Additionally, under current federal income tax law, federal net operating loss incurred in tax years beginning after December 31, 2017 may be carried forward indefinitely, but the deductibility of such federal net operating loss generally is limited to 80% of U.S. federal taxable income.

The Tax Cuts and Jobs Act ("TCJA") resulted in significant changes to the treatment of research and developmental ("R&D") expenditures under Section 174. For tax years beginning after December 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, 2024, we capitalized for tax purposes $11.3 million and $0.7 million of domestic and foreign R&D expenses, respectively.

To the extent that we continue to generate taxable losses, unused losses will carry forward to offset future taxable income, if any. We may be limited in the portion of net operating loss carry forwards and other tax attributes, such as research tax credits, that we can use in the future to offset taxable income for U.S. federal and state income tax purposes. Under Sections 382 and 383 of the United States Internal Revenue Code of 1986, as amended ("Code"), and corresponding provisions of state law, if a corporation undergoes an "ownership change" (generally defined as a greater than 50-percentage-point cumulative change (by value) in the equity ownership of certain stockholders over a rolling three-year period), the corporation's ability to use its pre-change net operating loss carry forwards and other pre-change tax attributes, such as research tax credits, to offset its post-change taxable income or taxes may be limited. We preliminarily determined that we experienced ownership changes in connection with our June 2021 Offering, and October 2024 Offering and may do so in the future as a result of subsequent shifts in our stock ownership, some of which are outside our control including, without limitation, the exercise of the Series A-1 Warrants or the Series B Warrants under the October 2024 Offering. Our net operating loss carry forwards may also be subject to limitation under state laws. Further, our ability to utilize net operating loss carry forwards of companies that we may acquire in the future may also be subject to limitations. As a result, even if we attain profitability, we may be unable to use a material portion of our net operating loss and other tax attributes, such as research tax credits, which could adversely affect our future cash flows.

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

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

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

Our results of operations have been adversely affected and, in the future, could be materially adversely impacted by future epidemics and pandemics.

Our business and results of operations could be adversely impacted by future epidemics or pandemics, such as we observed with COVID-19, particularly if there are closures or other restrictions in the places where we or our manufacturers and suppliers operate. For example, we have in the past and may in the future experience impacts to certain of our suppliers as a result of epidemics or pandemics or other health outbreaks occurring in one or more of locations, which may materially and adversely affect our business, financial condition and results of operations. Further, our operation has in the past and may in the future experience disruptions, including in connection with temporary office closures and suspension of services by our suppliers, which may result in us having to procure the components for our product candidates from alternate suppliers, which may materially and adversely affect our development timelines, and our business, financial condition and results of operations. Future epidemics and pandemics may also have adverse consequences for clinical trials, including the drop-out of subjects or inability to attract subjects.

Inadequate funding for the NIH, FDA, the SEC and other government agencies, including from government shutdowns, policy or administrative changes or other disruptions to these agencies' operations, could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

Currently, federal agencies in the U.S. are operating under a continuing resolution that is set to expire on September 30, 2025. Without appropriation of additional funding to federal agencies, our business operations related to our product development activities for the U.S. market could be impacted. Government funding is subject to the political process, which is inherently fluid and unpredictable. Under the Trump administration, the NIH announced on February 7, 2025, a policy significantly reducing research grants by limiting payments for indirect costs. Indirect costs represented more than 25% of total grant dollars awarded by the NIH in 2023. We may face increased financial pressure due to this change or any future caps on indirect costs. While, as of the date of this filing, the order has been temporarily stayed, there can be no assurance that it will not take effect or that other adverse actions will not be taken involving NIH-related grant funding

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, the ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new product candidates to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

Risks Related to Ownership of Our Common Stock

The market price of our common stock may be volatile.

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

- results of our preclinical studies and clinical trials, or regulatory status of our product candidates;
- results of preclinical studies, clinical trials, or regulatory approvals of product candidates of our competitors, or announcements about new research programs or product candidates of our competitors;
- delays in filing our INDs, commencing trials, or objections by the FDA as to the content of our INDs;

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

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

Commencing December 31, 2025, we will no longer qualify as an "emerging growth company" as defined in the JOBS Act, and the reduced disclosure requirements applicable to emerging growth companies will no longer apply to us.

As of December 31, 2025, we will no longer qualify as an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012 ("JOBS Act"). As such, we will incur significant additional expenses that we did not previously incur in complying with the Sarbanes-Oxley Act of 2002 and rules implemented by the SEC. We will become subject to certain disclosure requirements that are applicable to other public companies that were not applicable to us as an emerging growth company, for example, 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 consolidated financial statements and compliance with the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

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

on our Common Stock) or a public float (based on our Common Stock) that is less than $700 million, annual revenues of $100 million or more during the most recently completed fiscal year.

As a result, the information we provide stockholders will be different than the information that is available with respect to other public companies. At the time of writing this, we have not included all of the executive compensation related information that would be required if we were not an emerging growth company, nor have we included all of the quantitative and qualitative disclosures about market risk that would be required if we were not a smaller reporting company. We cannot predict whether investors will find our common stock less attractive if we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock, and our stock price may be more volatile. Additionally, we expect that our loss of "emerging growth company" status will require additional attention from management and will result in increased costs to us, which could include higher legal fees, accounting fees and fees associated with investor relations activities, among others.

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

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

Pursuant to Section 404 of SOX, we are required to furnish a report by our management on our internal control over financial reporting. 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, we are 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.

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 ("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 us shall not apply to suits seeking to enforce a duty or liability created by the Securities Act or the Exchange Act.

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

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

We are subject to the periodic reporting requirements of the Exchange Act. Our disclosure controls and procedures are designed to reasonably assure that information required to be disclosed by us in reports we file or submit under the Exchange Act are accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in

the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

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

General Risk Factors

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

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

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

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

It cannot be predicted whether, when, in what form, or with what effective dates, new tax laws may be enacted, or regulations and rulings may be enacted, promulgated or issued under existing or new tax laws, which could result in an increase in our or our shareholders' tax liability or require changes in the manner in which we operate in order to minimize or mitigate any adverse effects of changes in tax law or in the interpretation thereof. We urge investors to consult with their legal and tax advisers regarding the implications of potential changes in tax laws on an investment in our common stock.

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

We may engage in various acquisitions and strategic partnerships in the future, including licensing or acquiring complementary products, intellectual property rights, technologies, or businesses. For example, in February 2025 we acquired CorHepta and issued shares of our common stock as consideration, which diluted our stockholders. 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 ("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, criminals actions against us, our officers, or our employees, the closing down of our facilities, requirements to obtain export licenses, cessation of business activities in sanctioned countries, implementation of compliance programs, and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our products in one or more countries and could materially damage our reputation, our brand, our international expansion efforts, our ability to attract and retain employees, and our business, prospects, operating results, and financial condition.

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

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

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

Significant political, trade, or regulatory developments, such as those stemming from the change in U.S. federal administration, are difficult to predict and may have a material adverse effect on us. Similarly, changes in U.S. federal policy that affect the geopolitical landscape could give rise to circumstances outside our control that could have negative impacts on our business operations. For example, on February 1, 2025, the U.S. imposed a 25% tariff on imports from Canada and Mexico, which were subsequently suspended for a period of one month, and a 10% additional tariff on imports from China. Historically, tariffs have led to increased trade and political tensions. In response to tariffs, other countries have implemented retaliatory tariffs on U.S. goods. Political tensions as a

result of trade policies could reduce trade volume, investment, technological exchange and other economic activities between major international economies, resulting in a material adverse effect on global economic conditions and the stability of global financial markets. Any changes in political, trade, regulatory, and economic conditions, including U.S. trade policies, could have a material adverse effect on our financial condition or results of operations. These and other risks associated with conducting business internationally may materially adversely affect our ability to attain profitable operations.

Item 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity.

Risk Management and Strategy

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

Our cybersecurity program is focused on the following areas:

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

Risks from Cybersecurity Threats

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

Board Oversight of Cybersecurity Risks

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

Management's Role in Assessing and Managing Cybersecurity Risks

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

Item 2. Properties.

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

Item 3. Legal Proceedings.

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

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

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

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

Holders of Record

Equiniti Trust Company, LLC (formerly known as American Stock Transfer & Trust Company, LLC) is the transfer agent for our common stock. As of March 21, 2025, there were 29 holders of record of our common stock. Not reflected in the number of stockholders of record are persons who beneficially own shares of common stock held in nominee or street name.

Dividends

We have never previously declared or paid any cash dividends on our capital 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.

Securities Authorized for Issuance Under Equity Compensation Plans

Information about securities authorized for issuance under our equity compensation plans is incorporated herein by reference to Part III, Item 12 of this Annual Report.

Repurchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

Item 6. [Reserved]

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

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

Overview

We are a clinical-stage pharmaceutical company developing therapeutics to modify the course of cardiopulmonary and other diseases including those that arise from aberrant signaling through the Abelson Tyrosine Kinase, and type III receptor tyrosine kinases including platelet derived growth factor receptors and c-KIT. The Company's multi-therapeutic pipeline is developing IKT-001, a prodrug of imatinib mesylate, for Pulmonary Arterial Hypertension ("PAH"). We have completed non-human primate safety studies and a bioequivalence clinical trial in healthy volunteers to determine the doses of IKT-001 that are equivalent to imatinib mesylate and the results are being utilized to set the doses in a Phase 2b trial to determine if IKT-001 could be a disease-modifying treatment for PAH. We have also developed risvodetinib (also known as IkT-148009), a selective inhibitor of the non-receptor Abelson Tyrosine Kinases that targets the treatment of Parkinson's disease inside and outside the brain. In 2021, we commenced clinical development of risvodetinib. In 2023, we initiated the Phase 2 201 trial ("201 Trial") for risvodetinib (IkT-148009) as a treatment for Parkinson's disease and completed that trial on October 6, 2024. In January 2025, we reported results from the 201 Trial and decided to pause further development of risvodetinib as we focus our resources on advancing lead program IKT-001 in PAH. We will consider our strategic options for the risvodetinib program.

IKT-001 and PAH

IKT-001 emerged from the Company's medicinal chemistry program that aimed to develop improvements to drugs that inhibit Abelson Tyrosine Kinase and type III receptor tyrosine kinases. IKT-001, a prodrug of imatinib mesylate, was designed to improve areas of the molecule that might play a role in the gastrointestinal ("GI") side effects commonly observed with oral imatinib mesylate, the current standard of care. A three-part dose finding/dose equivalence study in 66 healthy volunteers (known as 'the 501 trial') was completed with IKT-001 in 2023. The study was designed to evaluate the 96-hour single-dose pharmacokinetics of imatinib delivered as IKT-001 and determine the dose relationship between IKT-001 and imatinib mesylate. Based on this study it was determined that bioequivalence was established with a 300 mg dose of IKT-001 to a dose of 230 mg of imatinib mesylate while a 500 mg dose of IKT-001 was established as bioequivalent to a dose of 383 mg of imatinib mesylate. These doses are adequate to cover the target systemically and were similar to the doses of imatinib mesylate used in the Phase 3 IMPRES trial in PAH.

On January 19, 2024, we met with the Food and Drug Administration ("FDA") Hematological Malignancy Review Team ("Review Team") in a Pre-New Drug Application ("pre-NDA"), meeting to discuss our bioequivalence studies of IKT-001 and its path to approval. All questions were addressed and summarized in official meeting minutes the issued by the FDA on February 12, 2024. During the meeting, we inquired whether additional clinical studies would be needed to seek approval and discussed manufacturing and quality control requirements for approval. The Review Team acknowledged that the 505(b)(2) pathway appeared to be the appropriate pathway for approval of IKT-001. The Review Team also discussed the possible difference between IKT-001 and imatinib mesylate absorption in the gut and recommended that we evaluate whether IKT-001 and imatinib mesylate behave differently with respect to certain gut transporters that regulate absorption. This evaluation was completed and determined that IKT-001 and imatinib mesylate have similar behavior toward the transporters P-glycoprotein ("PGP") and the Breast Cancer Resistance Protein ("BCRP"). Finally, a number of recommendations were discussed to prevent the potential mix-up between IKT-001 and imatinib mesylate either at the pharmacy or by patients for two drugs delivering the same active ingredient. The Company discussed alternate dosage forms for IKT-001 relative to imatinib mesylate as the primary mitigation strategy and will provide a justification of the dosage forms chosen and why they are unlikely to cause medication errors if/when the Company submits a New Drug Application ("NDA") for approval of IKT-001 in these cancer indications.

PAH is a rare disease of the pulmonary microvasculature found in 15 to 50 persons per million within the United States and Europe. The global PAH market size was valued at $7.66 billion in 2023 and is estimated to grow at a compound annual growth rate of 5.4% between 2024 to 2030. Most of the treatments that constitute the standard of care (e.g. ERAs, PDE5s, prostacyclins) primarily act as vasodilators. In 2024, sotatercept was approved for the treatment of PAH on top of SOC. Sotatercept is recombinant fusion protein

that acts as a trap for transforming growth factor-beta superfamily ligands, including activin A and bone morphogenetic protein 9. These ligands may play a role in the development and progression of PAH by promoting cell proliferation and fibrosis.

The success of sotatercept has created renewed enthusiasm around the anti-proliferative pathways in PAH. As previously mentioned, imatinib inhibits Abelson Tyrosine Kinase and type III receptor tyrosine kinases and through these pathways inhibits Platelet-derived growth factor receptor which is involved in cell proliferation and angiogenesis as well as Stem cell factor receptor which targets mast cells and other hematopoietic progenitors. Through these targets imatinib may inhibit vascular smooth muscle cell proliferation and fibrosis. This pathway may provide an alternate pathway for disease modification in PAH.

The first reports of the use of imatinib in PAH were published in 2005 and 2006. A phase 2, RCT was subsequently conducted showing clinical benefit of imatinib in PAH. In 2013, the outcome of a Phase 3 trial (IMPRES) evaluating imatinib mesylate as a treatment for PAH was reported, demonstrating that imatinib may improve key parameters associated with PAH. In this study imatinib improved exercise capacity and hemodynamics in patients with advanced PAH but approval was precluded because of the bleeding risk associated with concomitant anti-coagulant therapy and the high discontinuation rate in the imatinib group.

As we considered revisiting the use of imatinib in PAH, we recognized that changes in standard-of-care for these patients may have alleviated much of the safety risk previously observed for imatinib in PAH patients. This analysis prompted us to file a pre-IND ("PIND") meeting request to discuss the application of IKT-001 as a potential disease-modifying treatment for PAH. To evaluate this further, members of the Company met with the FDA Division of Cardiology and Nephrology in a PIND meeting to discuss our plan to utilize IKT-001 in a Phase 2b efficacy, safety and tolerability study in PAH. At the meeting, the FDA confirmed that IKT-001 would be viewed as a New Molecular Entity ("NME") and that the appropriate path for approval remained to be the 505(b)(2) statute. This opens up the possibility of IKT-001 being granted NME status and market exclusivity on approval. The FDA requested at the PIND meeting that we conduct a comparative cell-culture based study of the human Ether-a-go-go-related Gene ("hERG") ion channel, a standard cardiovascular safety test performed for any NME for which a new Investigative New Drug Application ("IND") is to be opened. Neither IKT-001 nor imatinib mesylate were found to be inhibitors of hERG. Following completion of this study, the IND was filed with the FDA on August 9, 2024 and we were cleared to initiate a Phase 2b trial on September 9, 2024. On October 21, 2024, we closed a private placement with gross proceeds of approximately $110 million, before deducting placement fees and offering expenses, to support this program. If the warrants issued in such offering are exercised for cash, the total gross proceeds from the financing may be up to $275 million. We intend to use the net proceeds from the private placement to finance the initiation of a Phase 2b trial in PAH and for general corporate purposes. We have had discussions with the FDA regarding Orphan Drug Designation ("ODD") for delivery of imatinib by IKT-001 for PAH and plan to apply for ODD once the required pre-clinical studies are complete.

We currently have commercialization rights to all of our development programs and patent protection in the United States until 2033 for IKT-001 with upcoming patent application filings potentially extending patent protection for certain methods of treatment using IKT-001 until 2045.

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 60% and 67% of our operating expenses for the years ended December 31, 2024 and 2023, 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 contract research organizations ("CROs"), preclinical testing organizations, clinical testing organizations, contract manufacturing organizations ("CMOs"), academic and non-profit institutions and consultants;
- fees related to our license and collaboration agreements;
- personnel related expenses, including salaries, benefits and non-cash stock-based compensation expense; and
- other expenses, which include direct and allocated expenses for laboratory, facilities and other costs.

A portion of our research and development expenses are direct external expenses, which we track on a program-specific basis from inception of the program.

Program expenses include expenses associated with our most advanced product candidates and the discovery and development of compounds that are potential future candidates. We also track external expenses associated with our third-party research and development efforts. All external costs are tracked by therapeutic indication. We do not track personnel or other operating expenses incurred for our research and development programs on a program-specific basis. These expenses primarily relate to salaries and benefits and stock-based compensation and office consumables.

At this time, we can only estimate the nature, timing and costs of the efforts that will be necessary to complete the development of, and obtain regulatory approval for, any of our product candidates. We are also unable to predict when, if ever, material net cash inflows will commence from sales or licensing of our product candidates. This is due to the numerous risks and uncertainties associated with drug development, including the uncertainty of:

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

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

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

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

	Year ended December 31,		
	2024	2023	Change
PD	$ 9,333,359	$ 9,036,750	$ 296,609
PAH	1,672,869	—	1,672,869
Other research and development expenses	6,204,320	4,581,598	1,622,722
Total research and development expenses	$ 17,210,548	$ 13,618,348	$ 3,592,200

Selling, General and Administrative

Selling, general and administrative expenses include personnel related expenses, such as salaries, benefits, travel and non-cash stock-based compensation expense, expenses for outside professional services and allocated expenses. Outside professional services consist of legal, accounting and audit services and other consulting fees. Allocated expenses consist of rent expenses related to our offices in Lexington, Massachusetts and Atlanta, Georgia not otherwise included in research and development expenses.

We expect to incur additional expenses as a result of operating as a public company, including expenses related to compliance with the rules and regulations of the Securities and Exchange Commission ("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 are also increasing our administrative headcount as a public company and as we advance our product candidates through clinical development, which will also likely require us to increase our selling, general and administrative expenses.

Results of Operations

Comparison of the Years Ended December 31, 2024 and 2023

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

	Year ended December 31,		Change	
	2024	2023	($)	(%)
Grant revenue	$ —	$ 260,501	$ (260,501)	(100.0)
Research and development	(17,210,548)	(13,618,348)	(3,592,200)	26.4
Selling, general and administrative	(11,378,520)	(6,731,945)	(4,646,575)	69.0
Loss from operations	(28,589,068)	(20,089,792)	(8,499,276)	(42.3)
Interest income	1,069,182	1,060,909	8,273	0.8
Net loss	$ (27,519,886)	$ (19,028,883)	$ (8,491,003)	(44.6)

Grant Revenue

Grant revenue for the year ended December 31, 2024 decreased by $260,501 or 100.0% to $0 from $260,501 in the prior year. The Company has no active grants during the period ended December 31, 2024.

Research and Development

Research and development expenses increased by $3,592,200 or 26.4% to $17,210,548 from $13,618,348 in the prior year. The $3.6 million increase was due to an increase of $4.5 million in stock-based compensation, an increase of $1.7 million in PAH expenses, a $0.3 million increase in risvodetinib (IkT-148009) expenses partially offset by a net decrease of $2.9 million in all other research and development activities.

Selling, General and Administrative

Selling, general and administrative expenses increased by $4,646,575 or 69.0% to $11,378,520 from $6,731,945 in the prior year. The $4.6 million increase was primarily driven by an increase of $3.1 million in stock-based compensation, a $2.0 million increase in legal, consulting and compliance related fees partially offset by a $0.3 million decrease in Directors and Officers ("D&O") insurance, a $0.5 million decrease in advertising and promotions and a net increase of $0.3 million in all other selling, general and administrative expenses.

Interest Income

Interest income increased by $8,273 or 0.8% to $1,069,182 from $1,060,909 in the prior comparable period. The increase was driven by interest earned on our cash, cash equivalents and marketable securities.

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.

At December 31, 2024, the Company had cash, cash equivalents, and marketable securities of $97,543,528.

The Company has incurred recurring losses and at December 31, 2024 had an accumulated deficit of $94,420,611.

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 $94,420,611 at December 31, 2024. 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.

We believe that our existing cash, cash equivalents and marketable securities as of December 31, 2024 will enable us to fund our operating requirements for at least the next twelve months following the date of this Annual Report. 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;
- 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;
- the costs and ongoing investments to in-license and/or acquire additional technologies; and
- 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 epidemics or pandemics.

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 years presented below:

	Year ended December 31,	
	2024	**2023**
Net cash used in operating activities	$ (19,148,067)	$ (18,085,043)
Net cash (used in) provided by investing activities	(37,004,201)	11,656,666
Net cash provided by financing activities	103,477,668	8,405,003
Net increase in cash and cash equivalents	$ 47,325,400	$ 1,976,626

Net Cash Flows Used in Operating Activities

Net cash flows used in operating activities for the year ended December 31, 2024 totaled $19,148,067, and consisted primarily of a net loss of $27.5 million adjusted for non-cash stock compensation of $8.1 million, a decrease in prepaid expenses and other assets of $0.6 million, an increase in accounts payable of $0.3 million, an increase in accrued expenses and other current liabilities of $0.4 million and an increase in prepaid research and development of $0.1 million.

Net cash flows used in operating activities for the year ended December 31, 2023 totaled $18,085,043, and consisted primarily of a net loss of $19.0 million adjusted for non-cash stock compensation of $0.5 million, depreciation and lease expense of $0.2 million, increase in prepaid expenses and other assets of $0.1 million, decrease in accounts payable of $0.5 million, decrease in prepaid research and development of $0.9 million and a decrease in accrued expenses and other current liabilities of $0.1 million.

Cash (Used in) Provided by Investing Activities

Net cash flows used in investing activities for the year ended December 31, 2024, totaled $37,004,201, of which $60.5 million was used for the purchase of marketable securities investments and $23.5 million was provided by maturity of marketable securities.

Net cash flows provided by investing activities for the year ended December 31, 2023, totaled $11,656,666, of which $29.4 million was used for the purchase of marketable securities investments and $41.1 million was provided by maturity of marketable securities.

Cash Provided by Financing Activities

Net cash provided by financing activities for the year ended December 31, 2024 totaled $103,477,668, which consisted of $3.8 million of net proceeds from issuance of common stock and pre-funded warrants in connection with our May 2024 Offering and our ATM Offering and $99.6 million of net proceeds from issuance of common stock and pre-funded warrants in connection with our October 2024 Offering.

Net cash provided by financing activities for the year ended December 31, 2023 totaled $8,405,003, which consisted of $8.5 million net from the issuance of common stock and pre-funded warrants and $0.1 million of deferred offering costs.

Contractual Obligations and Commitments

On April 18, 2022, the Company entered into an operating lease agreement through September 30, 2025 for its office space in Lexington, Massachusetts. 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 $114,966, consisting of minimum annual rental obligations of $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 consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States ("GAAP"). The preparation of these consolidated 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 consolidated 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 consolidated financial statements included elsewhere in this Annual Report, we believe that the following accounting policies are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates.

Research and Development Expenses

We record research and development expenses to operations as incurred. Research and development expenses represent costs incurred by us for the discovery and development of our product candidates and the development of our RAMP™ drug discovery program and prodrug technologies and include: employee-related expenses, such as salaries, benefits, travel and non-cash stock-based compensation expense; external research and development expenses incurred under arrangements with third parties, such as CROs, preclinical testing organizations, clinical testing organizations, CMOs, academic and non-profit institutions and consultants; costs to acquire technologies to be used in research and development that have not reached technological feasibility and have no alternative future use; license fees; and other expenses, which include direct and allocated expenses for laboratory, facilities and other costs.

As part of the process of preparing consolidated 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 either the Black-Scholes-Merton option pricing model or the Monte Carlo option pricing model.

The intrinsic value of all in the money outstanding options as of December 31, 2024 was approximately $31.1 million, based on the closing price of our common stock of $3.25 per share at December 31, 2024, and $15.8 million of the intrinsic value of options was exercisable.

JOBS Act

The Jumpstart Our Business Startups Act of 2012 (“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 $1.235 billion or more; (ii) the date on which we are deemed to be a “large accelerated filer” under the rules of the SEC with at least $700.0 million of outstanding equity securities held by non-affiliates; (iii) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the previous three years; or (iv) the last day of our fiscal year following the fifth anniversary of the date of the completion of our December 2020 public offering.

Recent Accounting Pronouncements

The JOBS Act permits an emerging growth company such as us to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies until those standards would otherwise apply to private companies. We have elected not to “opt out” of such extended transition period, which means that when a standard is issued or revised and it has different application dates for public or private companies, we will adopt the new or revised standard at the time private companies adopt the new or revised standard and will do so until such time that we either (i) irrevocably elect to “opt out” of such extended transition period or (ii) no longer qualify as an emerging growth company. Unless otherwise discussed below, the Company does not believe that the adoption of recently issued standards has had or may have a material impact on the Company's consolidated financial statements or disclosures

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

As a smaller reporting company, we are not required to provide disclosure regarding quantitative and qualitative market risk.

Item 8. Financial Statements and Supplementary Data.

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

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

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed by us in the reports we file or submit under the Exchange Act, is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Our disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports we file under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

As of the end of the period covered by this Annual Report, management performed, with the participation of our principal executive and principal financial officers, an evaluation of the effectiveness of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act. Our disclosure controls and procedures are designed to ensure that information required to be disclosed in the reports we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC's forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, to allow timely decisions regarding required disclosures. Based on the evaluation, our principal executive and principal financial officers concluded that, as of December 31, 2024, our disclosure controls and procedures were effective.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as such term is defined in Exchange Act Rule 13a-15(f). Management evaluated the effectiveness of our internal control over financial reporting using the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO") in Internal Control Integrated Framework ("2013 Framework"). Based on this assessment, our management concluded that, as of December 31, 2024, our internal control over financial reporting was effective based on those criteria. All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation.

Attestation Report of the Registered Public Accounting Firm

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

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the fiscal quarter ended December 31, 2024 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

Rule 10b5-1 Trading Plans

None of our directors or officers (as defined in Rule 16a-1(f) of the Exchange Act) adopted or terminated a Rule 10b5-1 trading plan or arrangement or a non-Rule 10b5-1 trading plan or arrangement, as defined in Item 408(c) of Regulation S-K, during the three months ended December 31, 2024 covered by this Annual Report.

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

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this Item 10 will be included in our definitive proxy statement relating to our 2025 Annual Meeting of Stockholders, which we will file with the SEC within 120 days of the end of the fiscal year, and is incorporated herein by reference.

Our board of directors has adopted a Code of Business Conduct and Ethics applicable to all officers, directors, and employees, which is available on our website (https://www.inhibikase.com) under "Governance Documents." We intend to satisfy the disclosure requirement under Item 5.05 of Form 8-K regarding amendment to, or waiver from, a provision of our Code of Business Conduct and Ethics by posting such information on the website address and location specified above.

Item 11. Executive Compensation.

The information required by this Item 11 will be included in our definitive proxy statement relating to our 2025 Annual Meeting of Stockholders, which we will file with the SEC within 120 days of the end of the fiscal year, and is incorporated herein by reference.

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

The information required by this Item 12 will be included in our definitive proxy statement relating to our 2025 Annual Meeting of Stockholders, which we will file with the SEC within 120 days of the end of the fiscal year, and is incorporated herein by reference.

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

The information required by this Item 13 will be included in our definitive proxy statement relating to our 2025 Annual Meeting of Stockholders, which we will file with the SEC within 120 days of the end of the fiscal year, and is incorporated herein by reference.

Item 14. Principal Accountant Fees and Services.

The information required by this Item 14 will be included in our definitive proxy statement relating to our 2025 Annual Meeting of Stockholders, which we will file with the SEC within 120 days of the end of the fiscal year, and is incorporated herein by reference.

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, 2024 and 2023, 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, 2024 and 2023,and the results of its operations and its cash flows for each of the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

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

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

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

/s/ CohnReznick LLP

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

Holmdel, New Jersey

March 27, 2025

Inhibikase Therapeutics, Inc.
Consolidated Balance Sheets

	December 31, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 56,490,579	$ 9,165,179
Marketable securities	41,052,949	4,086,873
Prepaid research and development	81,308	219,817
Prepaid expenses and other current assets	826,473	739,179
Total current assets	98,451,309	14,211,048
Equipment and improvements, net	47,100	73,372
Right-of-use asset	101,437	222,227
Total assets	$ 98,599,846	$ 14,506,647
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 943,019	$ 646,767
Lease obligation, current	110,517	150,095
Accrued expenses and other current liabilities	2,680,030	2,259,955
Insurance premium financing payable	-	381,784
Total current liabilities	3,733,566	3,438,601
Lease obligation, net of current portion	-	90,124
Total liabilities	3,733,566	3,528,725
Commitments and contingencies (see Note 14)		
Stockholders' equity:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized; 0 shares issued and outstanding at December 31, 2024 and December 31, 2023	-	-
Common stock, $0.001 par value; 100,000,000 shares authorized; 69,362,439 and 6,186,280 shares issued and outstanding at December 31, 2024 and December 31, 2023	69,362	6,186
Additional paid-in capital	189,254,777	77,871,584
Accumulated other comprehensive (loss) income	(37,248)	877
Accumulated deficit	(94,420,611)	(66,900,725)
Total stockholders' equity	94,866,280	10,977,922
Total liabilities and stockholders' equity	$ 98,599,846	$ 14,506,647

See accompanying notes to consolidated financial statements.

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

	Year ended December 31,	
	2024	**2023**
Revenue:		
Grant revenue	$ —	$ 260,501
Total revenue	—	260,501
Costs and expenses:		
Research and development	17,210,548	13,618,348
Selling, general and administrative	11,378,520	6,731,945
Total costs and expenses	28,589,068	20,350,293
Loss from operations	(28,589,068)	(20,089,792)
Interest income	1,069,182	1,060,909
Net loss	(27,519,886)	(19,028,883)
Other comprehensive loss, net of tax		
Unrealized loss on marketable securities	(38,125)	(103,841)
Comprehensive loss	$ (27,558,011)	$ (19,132,724)
Net loss per share – basic and diluted	$ (1.16)	$ (3.16)
Weighted-average number of common shares – basic and diluted	23,712,220	6,028,210

See accompanying notes to consolidated financial statements.

Inhibikase Therapeutics, Inc.
Consolidated Statements of Stockholders' Equity

	Common Stock					
	Shares	Amount	Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
Balance at December 31, 2022	4,224,294	$ 4,224	$ 68,798,301	$ 104,718	$ (47,871,842)	$ 21,035,401
Stock-based compensation expense	—	—	500,148	—	—	500,148
Issuance of common stock, pre-funded warrants and warrants, net of issuance costs	1,961,986	1,962	8,573,135	—	—	8,575,097
Other comprehensive loss	—	—	—	(103,841)	—	(103,841)
Net loss	—	—	—	—	(19,028,883)	(19,028,883)
Balance at December 31, 2023	6,186,280	6,186	77,871,584	877	(66,900,725)	10,977,922
Stock-based compensation expense	—	—	8,140,617	—	—	8,140,617
Issuance of common stock, pre-funded warrants and warrants, net of issuance costs	63,176,159	63,176	103,242,576	—	—	103,305,752
Other comprehensive loss	—	—	—	(38,125)	—	(38,125)
Net loss	—	—	—	—	(27,519,886)	(27,519,886)
Balance at December 31, 2024	69,362,439	$ 69,362	$189,254,777	$ (37,248)	$ (94,420,611)	$ 94,866,280

See accompanying notes to consolidated financial statements.

Inhibikase Therapeutics, Inc.
Consolidated Statements of Cash Flows

	Year ended December 31,	
	2024	**2023**
Cash flows from operating activities		
Net loss	$ (27,519,886)	$ (19,028,883)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	26,272	177,398
Stock-based compensation expense	8,140,617	500,148
Non-cash consulting and marketing fees	—	31,536
Changes in operating assets and liabilities:		
Accounts receivable	—	39,881
Operating lease right-of-use assets	120,790	106,416
Prepaid expenses and other assets	(616,523)	(55,387)
Prepaid research and development	138,508	897,803
Accounts payable	271,782	(504,406)
Operating lease liabilities	(129,702)	(111,068)
Accrued expenses and other current liabilities	420,075	(138,481)
Net cash used in operating activities	(19,148,067)	(18,085,043)
Cash flows from investing activities		
Purchases of equipment and improvements	—	(14,238)
Purchases of investments - marketable securities	(60,455,103)	(29,426,101)
Maturities of investments - marketable securities	23,450,902	41,097,005
Net cash (used in) provided by investing activities	(37,004,201)	11,656,666
Cash flows from financing activities		
Proceeds from issuance of common stock, pre-funded warrants and warrants, net of issuance costs	103,477,668	8,543,559
Deferred offering costs	—	(138,556)
Net cash provided by financing activities	103,477,668	8,405,003
Net increase in cash and cash equivalents	47,325,400	1,976,626
Cash and cash equivalents at beginning of year	9,165,179	7,188,553
Cash and cash equivalents at end of year	$ 56,490,579	$ 9,165,179
Supplemental disclosures of cash flow information		
Insurance premium financing	$ -	$ 381,784
Issuance costs	$ 11,499,089	$ 1,456,479

See accompanying notes to consolidated financial statements.

Inhibikase Therapeutics, Inc.
Notes to Consolidated Financial Statements

1. Nature of Business

Inhibikase Therapeutics, Inc. is a clinical-stage pharmaceutical company developing protein kinase inhibitor therapeutics to modify the course of cardiopulmonary and neurodegenerative diseases and other diseases that arise from aberrant signaling through the Abelson Tyrosine Kinases. The Company's pipeline includes IkT-001, a prodrug of the anticancer agent imatinib, for the treatment of Pulmonary Arterial Hypertension. IkT-001 has completed bioequivalence dose calibration studies in preparation for a future late-stage trial in Pulmonary Arterial Hypertension (PAH).

Liquidity

As of December 31, 2024, the Company had cash, cash equivalents and marketable securities of $97,543,528.

The Company has incurred recurring losses and at December 31, 2024, had an accumulated deficit of $94,420,611.

To date, the Company has funded its operations primarily through public offerings of its common stock, private placements of its common stock and ATM sales. In December 2020, June 2021, January 2023, May 2024 and October 2024, the Company raised approximately $14.6 million, $41.1 million, $8.5 million, $3.2 million and $99.6 million, respectively, in net proceeds from its 2020 IPO, its June 2021 Offering, its January 2023 Offering, its May 2024 Offering and its October 2024 Offering, respectively and $0.5 million in ATM proceeds in 2024.

The Company is subject to a variety of risks similar to other early-stage life science companies including, but not limited to, the successful development, regulatory approval, and market acceptance of the Company's product candidates, development by its competitors of new technological innovations, protection of proprietary technology, and raising additional working capital. The Company has incurred significant research and development expenses, general and administrative expenses related to its product candidate programs and negative cash flows from operations. The Company anticipates costs and expenses to increase in the future as the Company continues to develop its product candidates.

The Company may seek to fund its operations, particularly with respect to its pulmonary arterial hypertension programs, 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. In addition, potential proceeds under the Series A-1 Warrants or the Series B-1 Warrants may not be available to the Company in a timely fashion, or at all. 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 October 2024 Offering has mitigated the Company's substantial doubt to continue as a going concern. The Company estimates that its cash and cash equivalents and marketable securities at December 31, 2024 is sufficient to fund its normal operations for at least the next twelve months from the date of issuance of these consolidated financial statements.

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, 2024 and 2023, have been prepared in accordance with the rules and regulations of the Securities and Exchange Commission ("SEC") and Generally Accepted Accounting Principles in the United States ("U.S. GAAP") for financial information, which prescribes elimination of all significant inter-company accounts and transactions in the accounts of the Company and its wholly owned subsidiary, IKT Securities Corporation, which was incorporated in the Commonwealth of Massachusetts in December 2021. In the opinion of management, these consolidated financial statements reflect all adjustments which are necessary for a fair statement of the Company's financial position and results of its operations, as of and for the periods presented. Any reference in these notes to applicable guidance is meant to refer to the authoritative U.S. GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Updates ("ASU") of the Financial Accounting Standards Board ("FASB").

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

Consolidation

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

Use of Estimates

The preparation of the Company's consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the consolidated 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.

No grant revenue was recognized for the year ended December 31, 2024. For the year ended December 31, 2023, the Company derived 100% of its total revenue from a single source, the United States Government, in the form of federal research grants.

Segment Information

Operating segments are defined as components of an enterprise for which separate discrete information is available for evaluation by the chief operating decision maker or decision-making group in deciding how to allocate resources and in assessing performance. The Company views is operations and manages its business as one operating and reporting segment, which is the business of developing protein kinase inhibitor therapeutics (See Note 16).

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 $56.5 million and $9.2 million at December 31, 2024 and 2023, 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 provision for credit losses, and the Company did not have any expected credit losses as of December 31, 2024 and 2023. The balance of accounts receivable as of December 31, 2022 was $39,881.

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 consolidated financial statements with assessing the amount, timing and uncertainty of cash flows arising from leases is required.

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

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

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

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

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

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

Equipment and Improvements

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

	Estimated Useful Econcomic Life
Leasehold property improvements, right-of-use assets	Lesser of lease term or useful life
Furniture and office equipment	5 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 (loss). Realized gains and losses, if any, are included in other income, net in the consolidated statements of operations and comprehensive loss.

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

Revenue Recognition

The Company generates revenue from research and development grants under contracts with third parties that do not create customer-vendor relationships. The Company's research and development grants are non-exchange transactions and are not within the scope of ASC Topic 606, *Revenue from Contracts with Customers* ("ASC 606"). Contribution revenue earned from activities performed pursuant to research and development grants is reported as grant revenue in the Company's consolidated statements of operations. Revenue from these grants is recognized as the Company incurs qualifying expenses as stipulated by the terms of the respective grant. Cash received from grants in advance of incurring qualifying expenses is recorded as deferred revenue. The Company records revenue and a corresponding receivable when qualifying costs are incurred before the grants are received.

Research and Development Costs

Costs incurred in the research and development of the Company's product candidates are expensed as incurred. Research and development expenses consist of costs incurred in performing research and development activities, including activities associated with performing services under grant revenue contracts and include salaries and benefits, stock compensation, research-related subcontractors and consultants, supplies and overhead costs. Advance payments made to suppliers and contract research organizations are classified as prepaid research and development and are expensed as research and development as the supplies are consumed and the contract services are provided. During the years ended December 31, 2024 and 2023 the company incurred expenses of approximately $307 thousand and $76 thousand, respectively with a related party vendor included in research and development expenses. As of December 31, 2024 and 2023, the Company had a payable balance with a related party vendor of approximately $0 and $14 thousand, respectively, included in accounts payable.

Stock-Based Compensation

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

The Company uses a Monte Carlo simulation to determine the fair value of complex option structures. For all non-complex option structures, 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 which includes Pre-Funded Warrants and shares held in abeyance from date of issuance, 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 ("JOBS Act"). The JOBS Act permits an emerging growth company such as the Company to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies until those standards would otherwise apply to private companies. The Company has elected not to "opt out" of such extended transition period, which means that when a standard is issued or revised and it has different application dates for public or private companies, the Company will adopt the new or revised standard at the time private companies adopt the new or revised standard and will do so until such time that it either (i) irrevocably elects to "opt out" of such extended transition period or (ii) no longer qualifies as an emerging growth company.

In November 2023, the FASB issued Accounting Standards Update No. 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures* which is intended to improve reportable segment disclosure requirements, primarily through enhanced disclosures about significant segment expenses. The new guidance is effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024, and early adoption is permitted. The Company adopted this standard as of January 1, 2024 and concluded it did not have a material impact on the Company's consolidated financial statements.

On December 14, 2023, the FASB issued ASU 2023-09, *Improvements to Income Tax Disclosures*, which amends the guidance in ASC 740, Income Taxes. The ASU is intended to improve the transparency of income tax disclosures by requiring (1) consistent categories and greater disaggregation of information in the rate reconciliation and (2) income taxes paid disaggregated by jurisdiction. It also includes certain other amendments to improve the effectiveness of income tax disclosures. The ASU's amendments are effective for public business entities for annual periods beginning after December 15, 2024. Entities are permitted to early adopt the standard "for annual financial statements that have not yet been issued or made available for issuance." Adoption is either prospectively or retrospectively; the Company will adopt this ASU on a prospective basis. The Company is currently evaluating the impact of the ASU, but does not expect any material impact upon adoption.

On November 2024, the FASB issued ASU 2024-03 - *Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses*. The ASU requires more detailed disclosures about the types of expenses in commonly presented expense captions such as cost of sales, selling, general and administrative expenses and research and development expenses. This includes separate footnote disclosure for expenses such as purchases of inventory, employee compensation, depreciation, and intangible asset amortization. Public business entities are required to apply the guidance prospectively and may apply it retrospectively. The ASU's amendments are effective for public business entities for annual periods beginning after December 15, 2026, and interim reporting periods beginning after December 15, 2027. Public

business entities are required to apply the guidance prospectively and may apply it retrospectively. The Company is currently evaluating the effect of adopting this ASU.

3. Supplemental Balance Sheet Information

Accrued expenses and other current liabilities consist of the following:

	December 31, 2024	December 31, 2023
Accrued consulting	$ 202,379	$ 49,395
Accrued compensation	999,303	635,451
Accrued research and development	1,397,348	1,472,292
Accrued other	81,000	102,817
Total accrued expenses and other current liabilities	$ 2,680,030	$ 2,259,955

4. Fair Value of Financial Instruments

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

	Fair Value Measurements as of December 31, 2024:			
	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	$ 11,238,598	$ —	$ —	$ 11,238,598
Total	$ 11,238,598	$ —	$ —	$ 11,238,598
Marketable securities, available-for-sale:				
U.S. Treasury obligations	$ 41,052,949	$ —	$ —	$ 41,052,949
Total	$ 41,052,949	$ —	$ —	$ 41,052,949

	Fair Value Measurements as of December 31, 2023:			
	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	$ 8,039,024	$ —	$ —	$ 8,039,024
Total	$ 8,039,024	$ —	$ —	$ 8,039,024
Marketable securities, available-for-sale:				
U.S. Treasury obligations	$ 4,086,873	$ —	$ —	$ 4,086,873
Total	$ 4,086,873	$ —	$ —	$ 4,086,873

5. Marketable Securities

Marketable securities consisted of the following:

December 31, 2024	Amortized Cost	Unrealized Gain	Unrealized Loss	Fair Value
Marketable securities, available-for-sale:				
U.S. Treasury obligations	$ 41,090,197	$ —	$ (37,248)	$ 41,052,949
Total	$ 41,090,197	$ —	$ (37,248)	$ 41,052,949

December 31, 2023	Amortized Cost	Unrealized Gain	Unrealized Loss	Fair Value
Marketable securities, available-for-sale:				
U.S. Treasury obligations	$ 4,085,996	$ 877	$ —	$ 4,086,873
Total	$ 4,085,996	$ 877	$ —	$ 4,086,873

As of December 31, 2024, the Company held seven U.S. Treasury debt securities that were in an unrealized loss position totaling $37,248. As of December 31, 2023, the Company held three U.S. Treasury debt securities that were in an unrealized gain position totaling $877. All U.S. treasury obligations were due to mature in less than one year for the years ended December 31, 2024 and 2023, respectively.

The Company received proceeds of $23.5 million from maturities of marketable securities for the year ended December 31, 2024. The Company received proceeds of $41.1 million from maturities of marketable securities for the year ended December 31, 2023.

6. Equipment and Improvements

Equipment and Improvements, net

	Year ended December 31,	
	2024	2023
Furniture and office equipment	$ 86,930	$ 86,930
IT equipment	16,895	16,895
	103,825	103,825
Less: Accumulated depreciation	56,725	30,453
Total	$ 47,100	$ 73,372

Depreciation expense for the year ended December 31, 2024 was $26,272. Depreciation expense for the year ended December 31, 2023 was $177,398.

7. Insurance Premium Financing Payable

	Year ended December 31,	
	2024	2023
AON	$ —	$ 381,784
Total insurance premium financing payable	$ —	$ 381,784

Insurance premium financing Payable to AON

In December 2023, the Company entered into an insurance premium financing and security agreement with AON Premium Finance, LLC (“AON”). Under the agreement, the Company financed $381,784 of certain premiums at an 8.59% annual interest rate. As of December 31, 2024 and December 31, 2023, the outstanding principal of the loan was $0 and $381,784, respectively, and is included on the balance sheet in Insurance premium financing payable. The final payment was paid in November 2024.

8. Stockholders’ Equity

Each share of common stock is entitled to one vote. The holders of common stock are also entitled to receive dividends whenever funds are legally available and when declared by the board of directors, subject to the prior rights of holders of all classes of stock outstanding. As of December 31, 2024, a total 15,106,412 shares of common stock were reserved for issuance upon the exercise of outstanding stock options and warrants under the 2020 Equity Incentive Plan and the 2011 Equity Incentive Plan.

Share Issuances

On October 21, 2024, the Company announced the closing of a private placement of approximately $110 million from the issuance and sale of shares of the Company's common stock and accompanying warrants with potential aggregate financing of up to approximately $275 million upon the full cash exercise of the warrants issued in the private placement, before deducting placement agent fees and offering expenses (“October 2024 Offering”). The October 2024 Offering consisted of (i) 58,310,000 shares of common stock sold at $1.37 per share, or, in lieu thereof, pre-funded warrants (“Pre-Funded Warrants”) to purchase up to 21,985,000 shares of common stock with an exercise price of $0.001, (ii) Series A-1 Warrants to purchase an aggregate of 40,139,474 shares of common stock with an exercise price of $1.37, or in lieu thereof, Pre-Funded Warrants to purchase the same number of shares of common stock (“Series A-1 Warrants”), and (iii) Series B-1 Warrants to purchase an aggregate of 73,813,529 shares of common stock with an exercise price of $1.37, or in lieu thereof, Pre-Funded Warrants to purchase the same number of shares of common stock (“Series B-1 Warrants”). The Pre-Funded Warrants and Pre-Funded Warrants underlying the Series A-1 Warrants and Series B-1 Warrants are exercisable at any time after their original issuance and will not expire. The Series A-1 Warrants and the Series B-1 Warrants will become exercisable at the earlier of (a) the 75th calendar day following the initial filing of the resale registration statement covering the resale of the shares of common stock issuable upon the exercise of the Series A-1 Warrants and Series B-1 Warrants, if the SEC notifies the Company that it will review such resale registration statement and (b) the 5th business day after the date the Company is notified by the SEC that such resale registration statement will not be subject to further review. Each Series A-1 Warrant will be exercisable for one share of common stock and will expire at 5:00 p.m. (New York City time) on the 30th day following the later of (a) the Company’s public announcement of the Phase 2b 12 week safety readout for IKT-001 for PAH and (b) the Company both obtaining stockholder approval for and filing an amendment to its charter to increase the number of authorized shares of common stock to a number of shares of common stock sufficient to allow for the full exercise of the warrants (“Charter Amendment”). Each Series B-1 Warrant will be exercisable for one share of common stock, will become exercisable by an investor once all of such investor’s Series A-1 Warrants have been exercised and will expire at 5:00 p.m. (New York City time) on the 30th day following the later of (a) the Company’s public announcement of its Phase 2b efficacy readout for IKT-001 with respect to PAH and (b) the Company both obtaining stockholder approval for and filing the Charter Amendment. The Series A-1 Warrants have an exercise price of $1.37 per share and the Series B-1 Warrants have an exercise price of $1.49 per share. The Company intends to use the net proceeds from the private placement to finance the initiation of a Phase 2b trial in PAH and for general corporate purposes. As of December 31, 2024, the Company had 19,815,131 pre-funded warrants outstanding.

On May 20, 2024, the Company entered into a securities purchase agreement with a single institutional investor in connection with a registered direct offering and concurrent private placement with the same institutional investor (collectively the "May 2024 Offering”). The May 2024 Offering consisted of (i) 714,527 shares of the Company's common stock sold at $1.68 per share, (ii) Pre-Funded Common Warrants to purchase up to 957,925 shares of common stock with an exercise price of $0.0001 which are immediately exercisable after the issuance until exercised in full, (iii) Series A Common Warrants to purchase 1,672,452 shares of common stock with an exercise price of $1.68 per share which expire on the one-year anniversary from the date of stockholder approval, and (iv) Series B Common Warrants to purchase 1,672,452 shares of common stock with an exercise price of $1.68 per share which expire on the five-year anniversary from the date of stockholder approval. All of the warrants in the May 2024 Offering were issued to a single investor. During the third quarter 2024, the investor exercised 247,925 Pre-Funded Common Warrants and exercised the remaining 710,000 Pre-Funded Common Warrants as of the date of this report. The Company received net proceeds from the May 2024 Offering of approximately $2.2 million.

On May 20, 2024, the Company also entered into a warrant inducement agreement with the same investor to exercise certain outstanding warrants that the Company issued in January 2023 (“January 2023 Existing Warrants”). Pursuant to the warrant inducement agreement, the investor agreed to exercise outstanding warrants to purchase an aggregate of 708,500 shares of the Company's common stock at an amended exercise price of $1.68 per share. These shares are held in abeyance and not considered outstanding. The shares held in abeyance will be held in abeyance until notice from the investor that the balance, or portion thereof, may be issued in compliance with a beneficial ownership limitation provision in the warrants. The Company also agreed to reduce the exercise price of the remaining unexercised portion of such warrants to purchase 1,229,484 shares of common stock to $1.68 per share and to issue the investor Series C Common Warrants to purchase 708,500 shares of the Company's common stock and Series D Common Warrants to purchase 708,500 shares of the Company's common stock (“January 2023 New Warrants”). Each will have an exercise price of $1.68 per share and will be exercisable beginning on the effective date of stockholder approval. The Series C Common Warrants will expire on the one-year anniversary from the date of stockholder approval and the Series D Common Warrants will expire on the five-year anniversary from the date of stockholder approval. The shares held in abeyance were all issued to the investor in 2024.

The repricing of the January 2023 Existing Warrants and issuance of the Series C Common Warrants and the Series D Common Warrants is considered a modification of the January 2023 Existing Warrants under the guidance of ASU 2021-04. The modification is consistent with the "Equity Issuance" classification under that guidance as the reason for the modification was to induce the holder to cash exercise their warrants, resulting in the imminent exercise of the January 2023 Existing Warrants, which raised equity capital and

generated net proceeds for the Company of approximately $1.0 million. The total fair value of the consideration of the modification includes the incremental fair value of the January 2023 Existing Warrants (determined by comparing the fair values immediately prior to and immediately after the modification) and the initial fair value of the January 2023 New Warrants. The fair values were calculated using the Black-Scholes model and the Company determined that the total fair value of the consideration related to the modification of the January 2023 Existing Warrants, including the initial fair value of the January 2023 New Warrants was $1.8 million.

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

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

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

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 ("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. On June 7, 2024, the stockholders of Registrant approved an amendment to the 2020 Plan, pursuant to which the number of shares of Common Stock reserved and available for issuance under the 2020 Plan increased by 2,500,000 shares. On January 3, 2025, the stockholders of the Company approved an amendment to the 2020 Plan, pursuant to which the number of shares of Common Stock reserved and available for issuance under the 2020 Plan increased by 27,453,993 shares. Subject to certain adjustments, the maximum number of shares of common stock that may be issued under the 2020 Plan after the stockholder's approval on January 3, 2025 in connection with awards is limited to 31,417,517 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

On October 9, 2024, the Company modified only the exercise price on all outstanding previously issued stock options. A total of 31 grantees were affected resulting in approximately $0.2 million of total incremental fair value expense recognized. The Company determined that the modification of the stock options, both vested and unvested, was a probable to probable (Type 1) modification. The Company recognized the grant date fair value and any incremental fair value on the modification date. For all options previously vested, all prior expense had been recognized and only the incremental fair value will be recognized. For the options not fully vested, any remaining grant date fair value plus the incremental fair value will be recognized ratably over the remaining vesting term.

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, 2022	732,395	$ 13.14	6.20
Granted	111,668	3.03	—
Exercised	—	—	—
Forfeited	(4,540)	10.74	—
Cancelled	—	—	—
Outstanding at December 31, 2023	839,523	11.90	5.30
Granted	17,219,692	1.42	
Exercised	—	—	—
Forfeited	(1,140,595)	9.11	—
Cancelled	(14,570)	12.15	—
Outstanding at December 31, 2024	16,904,050	1.41	9.48
Exercisable at December 31, 2024	7,962,036	1.26	9.31

As of December 31, 2024, the intrinsic value of options outstanding was $31.1 million and $15.8 million 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 2024 and the exercise price of each in the money stock option award. We adjust for actual forfeitures as they occur.

During the year ended December 31, 2024, certain performance conditions were met. There were no options to purchase stock that vested upon the achievement of performance conditions at December 31, 2023.

The weighted-average fair values of options granted in the years ended December 31, 2024 and 2023 were $0.62 and $3.03, per share, respectively, and were calculated using the following estimated assumptions:

	Year ended December 31,	
	2024	2023
Weighted-average risk-free interest rate	4.11%	4.27%
Expected dividend yield	0.00%	0.00%
Expected volatility	98.77%	98.45%
Expected terms	9.50 years	4.38 years

The total fair values of stock options that vested during the years ended December 31, 2024 and 2023 were $7,863,021 and $608,539, respectively.

As of December 31, 2024, there was $2,763,814 of total unrecognized compensation cost related to non-vested stock options granted under the 2011 Plan and the 2020 Plan. The Company expects to recognize that cost over a remaining weighted-average period of 1.57 years as of December 31, 2024.

Restricted Stock Units

During the years ended December 31, 2024 and 2023, there were no restricted stock units issued or outstanding.

Stock-Based Compensation Expense

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

	Year ended December 31,	
	2024	2023
Research and development	$ 4,692,169	$ 160,080
Selling, general and administrative	3,448,448	340,068
Total stock-based compensation expense	$ 8,140,617	$ 500,148

10. ATM Program

On May 16, 2022, the Company entered into an Equity Distribution Agreement ("Piper Agreement") with Piper Sandler & Co. as sales agent ("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 ("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.

Effective January 25, 2023, the Company terminated the Piper Agreement by providing a notice of termination to the Agent in accordance with the terms of the Equity Distribution Agreement. No shares were sold under the Piper Agreement prior to termination.

On February 1, 2024, the Company entered into an At the Market Offering Agreement ("ATM") with H.C. Wainwright & Co., LLC, as sales agent ("Agent"), pursuant to which the Company may, from time to time, issue and sell shares of its common stock, in an aggregate offering price of up to $5,659,255, through or to the Agent. Under the terms of the ATM Agreement with the Agent ("ATM Agreement"), the Agent may sell the shares of the Company's 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 of 1933, as amended. 315,338 shares of the Company's common stock were sold pursuant to the ATM Agreement for an aggregate gross sales price of $849,187. On May 20, 2024, the Company filed with the Securities and Exchange Commission a prospectus supplement to reduce the maximum aggregate gross sales price of its common stock that may be offered, issued and sold under the ATM Agreement from and after May 20, 2024 to $50,000, not including the shares of the Company's common stock previously sold. No sales of the Company's common stock pursuant to the ATM Agreement have occurred since this date. On December 2, 2024, the Company provided to the Agent a notice of termination of the ATM Agreement, with such termination to be effective December 11, 2024 in accordance with the terms of the ATM Agreement.

11. Warrants

On October 27, 2018, the Company granted a warrant to purchase 4.9% of its issued and outstanding shares of common stock at the time of the issuance of the warrant, or 66,811 shares. The warrant has a term of 7 years and is exercisable at $28.76 per share.

On January 1, 2019, the Company issued a seven-year warrant to a service provider to purchase 3,423 shares of the Company's common stock with an exercise price of $28.76 per share. The warrants vested immediately. The Company received legal services, as needed, during 2019 under an unwritten agreement with the service provider.

On March 31, 2020, the Company issued a warrant to purchase up to 4,371 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 $34.04 per share and has a seven-year contractual term.

On August 25, 2020, the Company granted a fully vested warrant to purchase up to 3,643 shares of its common stock to one of its consultants. The warrant is exercisable at a strike price of $35.42 per share and has a contractual term of seven years.

On August 25, 2020, the Company granted a warrant to purchase up to 25,000 shares of its common stock to one of its consultants. The warrant is exercisable at a strike price of $35.42 per share and has a contractual term of seven years.

On December 28, 2020, the Company issued a seven-year warrant to purchase up to a total of 17,073 shares of the Company's common stock with an exercise price of $60.00 per share to certain 2018 investors in consideration for completing the IPO later than March 2019 ("Late IPO Warrants").

The Company issued and sold to its underwriters warrants to purchase up to 15,000 shares of its common stock and up to 125,000 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 $75.00 per share of common stock. The June 2021 Offering warrant is exercisable beginning June 15, 2022 at an initial exercise price of $22.50 per share of common stock.

On June 15, 2021, the Company issued a warrant to purchase an aggregate of 125,000 shares of common stock for an aggregate purchase price of $100. The warrant has an initial exercise price of $22.50 per share of common stock and expires June 15, 2026.

On January 25, 2023, the Company issued warrants to purchase up to 1,937,985 shares of Common Stock with an exercise price of $5.16, and pre-funded warrants to purchase up to 1,471,187 shares of Common Stock with an exercise price of $0.06. The warrants will expire on January 27, 2028. The Company further issued warrants to purchase up to 67,830 shares of common stock with an exercise price of $1.68 and an expiration date of January 25, 2028. As of December 31, 2024 2,179,687 warrants were exercised.

On May 20, 2024, the Company issued pre-funded warrants to purchase up to 957,925 shares of common stock with an exercise price of $0.0001 which are immediately exercisable after the issuance until exercised in full, series A common warrants to purchase 1,672,452 shares of common stock with an exercise price of $1.68 per share which expire on the one-year anniversary from the date of stockholder approval, and series B common warrants to purchase 1,672,452 shares of common stock with an exercise price of $1.68 per share which expire on the five-year anniversary from the date of stockholder approval. All of the warrants in the May 2024 Offering were issued to a single investor. All of the pre-funded warrants were exercised in 2024.

On May 20, 2024, the Company also entered into a warrant inducement agreement with the same investor to exercise certain outstanding warrants that the Company issued in January 2023 ("January 2023 Existing Warrants"). Pursuant to the warrant inducement agreement, the investor agreed to exercise outstanding warrants to purchase an aggregate of 708,500 shares of the Company's common stock at an amended exercise price of $1.68 per share. These shares are held in abeyance and not considered outstanding. The shares held in abeyance will be held in abeyance until notice from the investor that the balance, or portion thereof, may be issued in compliance with a beneficial ownership limitation provision in the warrants. The Company also agreed to reduce the exercise price of the remaining unexercised portion of such warrants to purchase 1,229,484 shares of common stock to $1.68 per share and to issue the investor Series C Common Warrants to purchase 708,500 shares of the Company's common stock and Series D Common Warrants to purchase 708,500 shares of the Company's common stock ("January 2023 New Warrants"). Each will have an exercise price of $1.68 per share and will be exercisable beginning on the effective date of stockholder approval. The Series C Common Warrants will expire on the one-year anniversary from the date of stockholder approval and the Series D Common Warrants will expire on the five-year anniversary from the date of stockholder approval. As of December 2024, 708,500 abeyance shares were exercised.

On October 21, 2024, the Company issued pre-funded warrants to purchase up to 21,985,000 shares of common stock with an exercise price of $0.001, series A-1 warrants to purchase an aggregate of 40,139,474 shares of common stock with an exercise price of $1.37, or in lieu thereof, pre-funded warrants to purchase the same number of shares of common stock, and series B-1 warrants to purchase an aggregate of 73,813,529 shares of common stock with an exercise price of $1.37, or in lieu thereof, pre-funded warrants to purchase the same number of shares of common stock. The pre-funded warrants and pre-funded warrants underlying the series A-1 warrants and series B-1 warrants are exercisable at any time after their original issuance and will not expire. The series A-1 warrants and the series B-1 warrants will become exercisable at the earlier of (a) the 75th calendar day following the initial filing of the resale registration statement covering the resale of the shares of common stock issuable upon the exercise of the series A-1 warrants and series B-1 warrants, if the SEC notifies the Company that it will review such resale registration statement and (b) the 5th business day after the date the Company is notified by the SEC that such resale registration statement will not be subject to further review. Each series A-1 warrant will be exercisable for one share of common stock and will expire at 5:00 p.m. (New York City time) on the 30th day following the later of (a) the Company's public announcement of the Phase 2b 12 week safety readout for IKT-001 for PAH and (b) the Company both obtaining stockholder approval for and filing an amendment to its charter to increase the number of authorized shares of common stock to a number of shares of common stock sufficient to allow for the full exercise of the warrants ("Charter Amendment"). Each series B-1 warrant will be exercisable for one share of common stock, will become exercisable by an investor once all of such investor's series A-1 warrants have been exercised and will expire at 5:00 p.m. (New York City time) on the 30th day following the later of (a) the Company's public announcement of its Phase 2b efficacy readout for IKT-001 with respect to PAH and

(b) the Company both obtaining stockholder approval for and filing the Charter Amendment. The series A-1 warrants have an exercise price of $1.37 per share and the series B-1 warrants have an exercise price of $1.49 per share. As of December 31, 2024, 2,169,869 pre-funded warrants were exercised.

12. Net Loss Per Share

The following table presents the calculation of basic and diluted net loss per share applicable to common stockholders. Basic net loss per share is calculated by dividing net loss attributable to common shareholders by the weighted-average number of shares outstanding during the period which includes Pre-Funded Warrants and shares held in abeyance from date of issuance.

	Year ended December 31,	
	2024	2023
Numerator:		
Net loss	$ (27,519,886)	$ (19,028,883)
Denominator:		
Weighted-average number of common shares outstanding – basic and diluted	23,712,220	6,028,210
Net loss per share applicable to common stockholders – basic and diluted	$ (1.16)	$ (3.16)

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,	
	2024	2023
Options to purchase shares of stock	16,904,050	839,523
Warrants to purchase shares of stock	26,134,671	2,266,133
Total	43,038,721	3,105,656

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, 2024, 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 $46.5 million of federal net operating losses with no expiration. At December 31, 2024, the Company had state net operating loss carryforwards of approximately $36.1 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 Company is in the process of completing a Section 382 study through December 31, 2024, and preliminarily determined there were likely ownership changes on June 5, 2021 and October 21, 2024, which will result in annual base limitations. The limitations are still being finalized, though the analysis determined there will be sufficient annual limitation to allow for the absorption of pre-change NOLs, and therefore, the Company will not write them off. Conversely, the analysis provides that the Company's federal R&D credits will expire unutilized, and as a result, the Company has written off the deferred tax assets related to these credits.

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

	Year ended December 31,	
	2024	2023
Tax at statutory rate	21.00%	21.00%
State income taxes	2.98%	5.54%
Tax law change	(1.40)%	1.37%
Stock-based compensation	(2.42)%	(0.11)%
R&D Tax Credits	2.59%	5.75%
Other	0.02%	(0.05)%
Limitation on tax attributes	(6.56)%	0.00%
Change in valuation Allowance	(16.21)%	(33.50)%
Effective tax rate	0.00%	0.00%

On December 4, 2023, Massachusetts enacted supplemental tax law changes modifying the adoption of a single sales apportionment factor effective on January 1, 2025 to use the property and payroll factors if no sales factor exits. As required under ASC 740, the Company has accounted for the deferred tax impacts of this tax law change in the period the tax law was enacted, which has the impact of decreasing its state deferred tax assets. The impact of the tax law change is offset by a change in valuation allowance.

The significant components of the Company's deferred tax assets (liabilities) consist of the following at December 31, 2024 and 2023:

	2024	2023
Deferred tax assets:		
Net operating loss carryforwards	$ 12,320,874	$ 9,179,115
Capitalized research and development	6,895,747	5,669,202
Stock-based compensation	3,780,237	2,629,771
R&D tax credits carryforwards	—	1,093,839
Accrued expenses	218,802	187,393
Fixed assets	447	(1,966)
Other	1,728	1,827
Total deferred tax assets	23,217,835	18,759,181
Deferred tax asset valuation allowance	(23,217,835)	(18,759,181)
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 $4.5 million and $6.4 million for the years ended December 31, 2024 and 2023, respectively. The increases in 2024 and 2023 are primarily related to each year's taxable loss as well as the increase in stock-based compensation in 2024. The Company has no uncertain tax positions at December 31, 2024 and 2023 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 December 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, 2024, the Company capitalized for tax purposes $11.3 million and $0.7 million of domestic and foreign R&D expenses, respectively.

14. Commitments and Contingencies

Operating Leases

On April 18, 2022, the Company entered into an operating lease agreement for office space at its new location in Lexington, Massachusetts ("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 9 months. We have an option to extend the lease term for an additional three (3) years thereafter.

The Company accounts for the Office Lease under the provisions of ASU No. 2021-09, ASU 2018-10, and ASC 842. We recorded a right-of-use asset and a corresponding operating lease liability on the Company's consolidated balance sheets upon the accounting commencement date in August 2022. The lease liability was measured at the accounting commencement date utilizing 12% which is the Company's incremental borrowing rate. The right-of-use asset had a balance of $101,437 at December 31, 2024. The operating lease obligations totaled $110,517 at December 31, 2024, all of which is included under current liabilities. The Company recorded lease expense relating to the Office Lease of $141,182 and short-term payments of $21,959 for the year ended December 31, 2024 and lease expense relating to the Office Lease of $141,182 and short-term payments of $22,209 for the year ended December 31, 2023 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, 2024, 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, 2024, are presented by calendar year as follows:

Year		
2025	$	114,966
Total lease payments		114,966
Less: imputed interest		(4,449)
Present value of operating lease liabilities	$	110,517

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, 2024, and 2023, the Company had not experienced any material losses related to these indemnification obligations, and no material claims with respect thereto were outstanding. The Company does not expect significant claims related to these indemnification obligations and, consequently, concluded that the fair value of these obligations is negligible, and no related reserves were established.

License Agreements

Sphaera Pharma Pte. Ltd.

On March 2, 2012, we entered into a collaborative research and development agreement, ("Sphaera Agreement"), with Sphaera Pharma Pte. Ltd. ("Sphaera"), to collaborate on the development of the prodrug technology to be applied to protein kinase inhibitors

for oncology and non-oncology indications. Under the terms of the Sphaera Agreement, each party would retain its preexisting intellectual property, but any intellectual property conceived or reduced to practice under and certain results arising from the Sphaera Agreement would be assigned to us. On October 5, 2012, we and Sphaera amended the Sphaera Agreement to reflect joint patent applications in the U.S. and India by us and Sphaera for a series of novel compounds. While the underlying intellectual property would be jointly owned, we have the exclusive right to commercialize thirteen of the twenty-four linkers detailed in the filed patent applications ("Company Compounds"), including the linker attached to imatinib that comprises IKT-001 with the remaining nine linkers owned by Sphaera ("Sphaera Compounds"). Sphaera has the right to develop the Company Compounds for oncology indications but may not commercialize the Company Compounds unless we abandon the Company Compounds. We have notified Sphaera that we do not intend to abandon the Company Compounds. We do not currently have the right to develop the Sphaera Compounds. Additionally, if either party files an IND for a Company Compound that has been abandoned by the other party for an oncology indication in humans, the non-filing party is prohibited from developing such Company Compound. In 2023, Sphaera liquidated and transferred its interests to Pivot Holding LLC, a U.S. entity ("Pivot"). On September 30, 2024, the Company and Pivot agreed to amend the agreement and for the Company to pay $500,000 upon signing as well as payment of the following milestones by the Company. A one-time payment of $4.4 million upon FDA Approval (as described in the Sphaera Agreement) and a single low digit royalty on net sales of an FDA approved drug. The parties agreed that no further FDA Approval milestone payment(s) shall be due to Pivot in the event that the Company receives additional FDA Approval(s).

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

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 ("Simple IRA")

The Company established an individual retirement plan for employees effective January 1, 2013 under Section 408(p) of the Internal Revenue Code. The Simple IRA covers substantially all employees of the Company who received at least $5,000 in compensation from the Company during any two preceding years and are reasonably expected to receive at least $5,000 in compensation from the Company in the current year of participation. Subject to certain overall statutory limitations, the Company must match employee contributions up to 3% of employees' qualified compensation for the year. Company contributions under the Simple IRA were $59,905 and $59,511 for the years ended December 31, 2024 and 2023, respectively.

16. Segment Information

The Company views its operations and manages its business as one operating and reportable segment, which is the business of developing protein kinase inhibitor therapeutics. Consistent with the operational structure, the Chief Executive Officer, as the chief operating decision maker ("CODM"), manages and allocates resources on a consolidated basis using consolidated net income (loss) as a measure of profit/loss for the single reportable segment. This decision making process reflects the way in which the financial

information is regularly reviewed and used by the CODM to evaluate performance, set operational targets, forecast future financial results, and allocate resources.

	Year ended December 31,	
	2024	2023
Revenues and other income		
Grant income	$ —	$ 260,501
Costs and expenses:		
Research and development (excluding share-based compensation) expense:		
PAH	1,672,869	—
PD	9,333,359	9,036,750
Other programs	1,512,151	4,421,520
Selling, general and administrative (excluding share-based compensation)	7,930,072	6,391,875
Share-based compensation expense	8,140,617	500,148
Total costs and expenses	28,589,068	20,350,293
Loss from operations	(28,589,068)	(20,089,792)
Interest income	1,069,182	1,060,909
Net loss	$ (27,519,886)	$ (19,028,883)

17. Subsequent Events

On February 21, 2025 (“Closing Date”), the Company entered into an Agreement and Plan of Merger and Reorganization (“Merger Agreement”) with Project IKT Merger Sub, Inc., a Delaware corporation and wholly-owned subsidiary of the Company (“Merger Sub”), CorHepta Pharmaceuticals, Inc., a Delaware corporation (“CorHepta”), and Preston S. Klassen, solely in his capacity as sellers’ representative. Pursuant to the Merger Agreement, on the Closing Date, Merger Sub merged with and into CorHepta (“Merger”), with CorHepta surviving the Merger as a wholly-owned subsidiary of the Company. On the Closing Date, the Company paid consideration for CorHepta of $15.0 million, subject to a customary purchase price adjustment mechanism. The Company paid the purchase price pursuant to the issuance of an aggregate of 4,979,101 shares (“Consideration Shares”) of the Company’s common stock, par value $0.001 per share (“Common Stock”), to the former stockholders of CorHepta (“CorHepta Stockholders”), of which 3,319,397 were issued as upfront consideration (“Upfront Consideration”). 82,979 Consideration Shares of the Upfront Consideration were deposited in a twelve-month escrow for purposes of satisfying potential indemnity obligations of the CorHepta Stockholders under the Merger Agreement. The remaining Consideration Shares were issued as contingent consideration (“Contingent Consideration”), which will vest upon achievement of a certain milestone. If the vesting condition is not satisfied as of the first anniversary of the Closing Date, then the Contingent Consideration will be forfeited. The Company is currently evaluating the accounting implications for the Merger Agreement.

In January 2025, in connection with the October 2024 Offering, the Company issued 702,625 warrants with an exercise price of $1.7125 and an expiration date of January 25, 2028.

On January 3, 2025, the number of the Company's authorized shares of common stock was increased from 100,000,000 shares to 500,000,000 shares. Also, the number of authorized shares of common stock reserved for issue under the Company's 2020 Equity Incentive plan was increased by 27,453,993 shares.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(1) For a list of the financial statements included herein, see Index to the Consolidated Financial Statements on page F-1 of this Annual Report on Form 10-K, incorporated into this Item by reference.

(2) Financial statement schedules have been omitted because they are either not required or not applicable or the information is included in the consolidated financial statements or the notes thereto. Those financial statement schedules required to be filed by Item 8 of this form, and by paragraph (b) below.

(3) The information required by this Item is set forth on the exhibit index of this Annual Report on Form 10-K.

EXHIBIT INDEX

Exhibit Number	Description*	Where Located				Filed Herewith
		Form	File Number	Exhibit Number	Filing Date	
2.1†*	Agreement and Plan of Merger and Reorganization, dated February 21, 2025, by and among Inhibikase Therapeutics, Inc., Project IKT Merger Sub, Inc., CorHepta Pharmaceuticals, Inc. and Sellers' Representative					X
3.1	Amended and Restated Certificate of Incorporation of Inhibikase Therapeutics, Inc.	8-K	001-39676	3.1	12/29/2020	
3.2	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of Inhibikase Therapeutics, Inc.	8-K	001-39676	3.1	6/29/2023	
3.3	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of Inhibikase Therapeutics, Inc.	8-K	001-39676	3.1	01/06/2025	
3.4	Amended and Restated Bylaws of Inhibikase Therapeutics, Inc.	8-K	001-39676	3.2	12/29/2020	
4.1	Specimen common stock Certificate of the Registrant	S-1	333-240036	4.1	07/23/2020	
4.2	Form of Warrant to purchase common stock of the Registrant, issued to each of the members of the Scientific Advisory Board and the investor named in Schedule A thereto	S-1	333-240036	4.2	07/23/2020	
4.3	Warrant, issued by Inhibikase Therapeutics, Inc. to Kubera North America, Inc., dated October 5, 2018	S-1	333-240036	4.3	07/23/2020	
4.4	Warrant, issued by Inhibikase Therapeutics, Inc. to Francis E. McDaniel, dated January 1, 2019	S-1A	333-240036	4.4	09/15/2020	
4.5	Warrant, issued by Inhibikase Therapeutics, Inc. to Francis E. McDaniel, dated March 31, 2020	S-1	333-240036	4.5	07/23/2020	
4.6	Form of Representative's Warrant	S-1	333-240036	4.6	07/23/2020	
4.7	Form of Late IPO Warrant	S-1	333-240036	4.7	07/23/2020	
4.8	Form of Pre-Funded Warrant	8-K	001-39676	4.1	01/26/2023	
4.9	Form of Private Common Warrant	8-K	001-39676	4.2	01/26/2023	
4.10	Form of PIPE Pre-Funded Warrant	8-K	001-39676	4.3	01/26/2023	
4.11	Form of PIPE Common Warrant	8-K	001-39676	4.4	01/26/2023	
4.12	Form of Common Warrant	S-1A	333-278844	4.11	04/25/2024	
4.13	Form of Pre-Funded Warrant	S-1/A	333-278844	4.12	04/25/2024	
4.14	Form of Placement Agent Warrant	S-1A	333-278844	4.13	04/25/2024	
4.15	Form of Warrant Agency Agreement	S-1A	333-278844	4.14	05/09/2024	

4.16	Form of Pre-Funded Warrant	8-K	001-39676	4.1	05/20/2024
4.17	Form of Series A Warrant	8-K	001-39676	4.2	05/20/2024
4.18	Form of Series B Warrant	8-K	001-39676	4.3	05/20/2024
4.19	Form of Series C Warrant	8-K	001-39676	4.4	05/20/2024
4.20	Form of Series D Warrant	8-K	001-39676	4.5	05/20/2024
4.21	Form of Warrant Amendment	8-K	001-39676	4.6	05/20/2024
4.22	Form of Pre-Funded Warrant	8-K	001-39676	4.1	10/10/2024
4.23	Form of Series A-1 Warrant	8-K	001-39676	4.2	10/10/2024
4.24	Form of Series B-1 Warrant	8-K	001-39676	4.3	10/10/2024
10.1	Collaborative Research and Development Agreement, by and between Inhibikase Therapeutics, Inc. and Sphaera Pharma Pte. Ltd., dated February 29, 2012	S-1	333-240036	10.2	07/23/2020
10.2	First Amendment to Collaborative Research and Development Agreement, by and between Inhibikase Therapeutics Inc. and Sphaera Pharma Pte. Ltd., dated October 5, 2012	S-1	333-240036	10.3	07/23/2020
10.3#	2011 Equity Incentive Plan and forms of agreements thereunder	S-1	333-240036	10.4	07/23/2020
10.4#	2020 Equity Incentive Plan and forms of agreements thereunder	S-1/A	333-240036	10.5	12/04/2020
10.5#	Amendment No. 1 to Inhibikase Therapeutics, Inc. 2020 Equity Incentive Plan	S-8	333-284687	99.2	02/05/2025
10.6#	Amendment No. 2 to Inhibikase Therapeutics, Inc. 2020 Equity Incentive Plan	S-8	333-284687	99.3	02/05/2025
10.7#	Employment Agreement, by and between Inhibikase Therapeutics, Inc. and Milton H. Werner Ph.D., effective upon the completion of the Company's Initial Public Offering	S-1	333-240036	10.7	07/23/2020
10.8#	Employment Agreement, by and between Inhibikase Therapeutics, Inc. and Joseph Frattaroli, dated October 24, 2018	S-1	333-240036	10.8	07/23/2020
10.9	Form of Inhibikase Therapeutics, Inc. Directors and Officers Indemnification Agreement	S-1	333-240036	10.9	07/23/2020
10.10	Lease Agreement, dated June 5, 2020, by and between Inhibikase Therapeutics, Inc. and Regus Management Group, LLC	S-1	333-240036	10.14	07/23/2020
10.11	Form of Consulting Agreement	S-1	333-240036	10.15	07/23/2020
10.12	Form of Representative's Warrant Agreement	8-K	001-39676	4.1	06/16/2021
10.13#	Amendment dated March 3, 2022 to the Employment Agreement, by and between Inhibikase Therapeutics, Inc. and Milton H. Werner, Ph.D., dated December 28, 2020.	8-K	001-39676	10.1	03/08/2022
10.14#	Amendment dated March 3, 2022 to the Employment Agreement, by and between Inhibikase Therapeutics, Inc. and Joseph Frattaroli, dated October 24, 2018.	8-K	001-39676	10.2	03/08/2022
10.15	Form of Stock Option Grant Notice and Award Agreement	8-K	001-39676	10.3	03/08/2022
10.16	Securities Purchase Agreement, dated as of January 25, 2023 (Registered Direct)	8-K	001-39676	10.1	01/26/2023
10.17	Securities Purchase Agreement, dated as of January 25, 2023 (PIPE)	8-K	001-39676	10.2	01/26/2023
10.18	Registration Rights Agreement, dated as of January 25, 2023 (PIPE)	8-K	001-39676	10.3	01/26/2023

10.19#	Employment Agreement between Inhibikase Therapeutics, Inc. and Garth Lees-Rolfe, dated as of April 1, 2024	S-1	333-278844	10.18	04/19/2024	
10.20	Securities Purchase Agreement, dated as of May 20, 2024	8-K	001-39676	10.1	05/20/2024	
10.21	Placement Agency Agreement, dated as of May 20, 2024	8-K	001-39676	10.2	05/20/2024	
10.22	Inducement Letter, dated as of May 20, 2024	8-K	001-39676	10.3	05/20/2024	
10.23	Securities Purchase Agreement, dated as of October 9, 2024	8-K	001-39676	10.1	10/10/2024	
10.24	Form of Registration Rights Agreement	8-K	001-39676	10.2	10/10/2024	
10.25#	Form of Director Offer Letter	8-K	001-39676	10.4	10/10/2024	
10.26	Settlement Agreement, dated as of September 30, 2024	8-K	001-39676	10.5	10/10/2024	
10.27	Consulting Agreement, by and between Inhibikase Therapeutics, Inc. and Milton H. Werner, dated February 13, 2025					X
10.28#	Employment Agreement, by and between Inhibikase Therapeutics, Inc. and Mark Iwicki, dated February 14, 2025					X
10.29#	Employment Agreement, by and between Inhibikase Therapeutics, Inc. and Christopher Cabell, dated February 21, 2025					X
10.30	Form of Non-Qualified Stock Option Agreement (Non-Plan Inducement Grant)					X
19.1	Amended & Restated Insider Trading Policy					X
21.1	Subsidiaries of the Registrant					X
23.1	Consent of Independent Registered Public Accounting Firm.					X
24.1	Power of Attorney (included on signature)					X
31.1	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					X
31.2	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					X
32.1**	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002					
32.2**	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002					
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.					X
101.SCH	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Documents					X
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)					X

(#) A contract, compensatory plan or arrangement to which a director or executive officer is a party or in which one or more directors or executive officers are eligible to participate.

(†) Annexes, schedules and/or exhibits have been omitted pursuant to Item 601(a)(5) of Regulation S-K. The Registrant agrees to furnish supplementally a copy of any omitted attachment to the SEC on a confidential basis upon request.
(*) Portions of this exhibit (indicated by asterisks) have been omitted in accordance with Item 601(b)(10) of Regulation S-K.
(**) Furnished herewith.

Item 16. Form 10-K Summary

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this Annual Report to be signed on its behalf by the undersigned, thereunto duly authorized**.**

INHIBIKASE THERAPEUTICS, INC.

Date: March 27, 2025

By: /s/ MARK IWICKI
Mark Iwicki
Chief Executive Officer

POWER OF ATTORNEY AND SIGNATURES

KNOW ALL BY THESE PRESENT, that each individual whose signature appears below hereby constitutes and appoints each of Mark Iwicki and Garth Lees-Rolfe, as such person's true and lawful attorney-in-fact and agent with full power of substitution and resubstitution, for such person in such person's name, place and stead, in any and all capacities, to sign any and all amendments (including post-effective amendments) to this Annual Report, and to file the same, with all exhibits thereto, and all documents in connection therewith, with the Securities and Exchange Commission, granting unto each said attorney-in-fact and agent full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as such person might or could do in person, hereby ratifying and confirming all that any said attorney-in-fact and agent, or any substitute or substitutes of any of them, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Annual Report has been signed below by the following persons on behalf of the Registrant in the capacities and on the dates indicated.

Name	Title	Date
/s/ MARK IWICKI Mark Iwicki	Chief Executive Officer and Director (*Principal Executive Officer)*	March 27, 2025
/s/ GARTH LEES-ROLFE Garth Lees-Rolfe	Chief Financial Officer (*Principal Financial Officer and Principal Accounting Officer)*	March 27, 2025
/s/ ROBERTO BELLINI Roberto Bellini	Director	March 27, 2025
/s/ ROY FREEMAN, M.D. Roy Freeman, M.D.	Director	March 27, 2025
/s/ DAVID CANNER, PH.D. David Canner, Ph.D.	Director	March 27, 2025
/s/ DENNIS BERMAN Dennis Berman	Director	March 27, 2025
/s/ ARVIND KUSH Arvind Kush	Director	March 27, 2025
/s/ AMIT MUNSHI Amit Munshi	Director	March 27, 2025
/s/ VINCENT AURENTZ Vincent Aurentz	Director	March 27, 2025

BOARD OF DIRECTORS

Mark Iwicki
Chief Executive Officer and Director

Amit Munshi
Chairman of the Board of Directors, President and Chief Executive Officer of Orna Therapeutics, Inc.

Roberto Bellini
Managing Partner at BSQUARED Capital Inc.

Arvind Kush
Chief Financial and Chief Business Officer at Candid Therapeutics, Inc.

David Canner, Ph.D.
Partner at Soleus Capital

Dennis Berman
President of Molino Ventures

Vincent Aurentz
Former Executive Vice President and Chief Business Officer at Arena Pharmaceuticals Inc.

Roy Freeman, M.D.
Professor of Neurology at the Harvard Medical School

EXECUTIVE OFFICERS

Mark Iwicki
Chief Executive Officer and Director

Chris Cabell, M.D.
President and Head of Research and Development

David McIntyre
Chief Financial Officer

CORPORATE HEADQUARTERS
1000 N. West Street, Suite 1200
Wilmington, DE 19801*

INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM
CohnReznick LLP
Holmdel, New Jersey

INHIBIKASE INVESTOR RELATIONS
Michael Moyer
LifeSci Advisors
mmoyer@lifesciadvisors.com

** The Company changed its corporate headquarters on April 25, 2025.*