UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-K

(Mark one)
☒ 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: 001-42031

INHIBRX BIOSCIENCES, INC.

(Exact name of registrant as specified in its charter)

Delaware	**99-0613523**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
11025 N. Torrey Pines Road, Suite 140 La Jolla, California	**92037**
(Address of principal executive offices)	**(Zip Code)**

(858) 795-4220
(Registrant's telephone number, including area code)

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, par value $0.0001	INBX	The Nasdaq Global Market

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 Section 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, a 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 Act). Yes ☐ No ☒

As of June 30, 2024, the aggregate market value of the registrant's common stock held by non-affiliates of the registrant was approximately $169.4 million, based on the closing price of the registrant's common stock on the Nasdaq Global Market of $14.17 per share.

As of February 28, 2025, the registrant had 14,475,904 shares of common stock outstanding.

Documents Incorporated By Reference

The following documents (or parts thereof) are incorporated by reference into the following parts of this Form 10-K: Certain information required in Part III of this Annual Report on Form 10-K is incorporated from the Registrant's Proxy Statement for the 2025 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission.

INHIBRX BIOSCIENCES, INC.
ANNUAL REPORT ON FORM 10-K
For the Year Ended December 31, 2024

TABLE OF CONTENTS

		Page
Special Note Regarding Forward-Looking Statements		1
	Part I.	3
Item 1.	Business	3
Item 1A.	Risk Factors	33
Item 1B.	Unresolved Staff Comments	85
Item 1C.	Cybersecurity	85
Item 2.	Properties	87
Item 3.	Legal Proceedings	87
Item 4.	Mine Safety Disclosures	87
	Part II.	88
Item 5.	Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	88
Item 6.	Reserved	89
Item 7.	Management's Discussion and Analysis of Financial Condition and Results of Operations	90
Item 7A.	Quantitative and Qualitative Disclosures About Market Risk	103
Item 8.	Financial Statements and Supplementary Data	104
Item 9.	Changes in and Disagreements With Accountants on Accounting and Financial Disclosure	135
Item 9A.	Controls and Procedures	135
Item 9B.	Other Information	136
Item 9C.	Disclosure Regarding Foreign Jurisdictions that Prevent Inspections	136
	Part III	137
Item 10.	Directors, Executive Officers and Corporate Governance	137
Item 11.	Executive Compensation	137
Item 12.	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	137
Item 13.	Certain Relationships and Related Transactions, and Director Independence	137
Item 14.	Principal Accountant Fees and Services	137
	Part IV.	138
Item 15.	Exhibits and Financial Statement Schedules	138
Item 16.	Form 10-K Summary	140
Signatures		140

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K, or this Annual Report, contains express and implied forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. Except as otherwise indicated by the context, references in this Annual Report to "we," "us" and "our" are to the consolidated business of Inhibrx Biosciences, Inc., or the Company or Inhibrx. All statements other than statements of historical facts contained in this Annual Report are forward-looking statements. In some cases, you can identify forward-looking statements by words such as "anticipate," "believe," "contemplate," "continue," "could," "estimate," "expect," "intend," "may," "plan," "possible," "potential," "predict," "project," "design," "seek," "should," "target," "will," "would," or the negative of these words or other comparable terminology. These forward-looking statements include, but are not limited to, statements about:

- the design, initiation, timing, progress, results and costs of our research and development programs as well as our preclinical studies and clinical trials;
- our ability to advance therapeutic candidates into, and successfully complete, clinical trials;
- our interpretation of initial, interim or preliminary data from our clinical trials, including interpretations regarding disease control and disease response;
- the potential benefits of regulatory designations;
- the timing or likelihood of regulatory filings and approvals;
- the safety and therapeutic benefits of our therapeutic candidates;
- the commercialization of our therapeutic candidates, if approved;
- the pricing, coverage and reimbursement of our therapeutic candidates, if approved;
- our ability to utilize our technology platform to generate and advance additional therapeutic candidates;
- the implementation of our business model and strategic plans for our business and therapeutic candidates;
- our ability to successfully manufacture our therapeutic candidates for clinical trials and commercial use, if approved;
- our ability to contract with third-party suppliers and manufacturers and their ability to perform adequately;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our therapeutic candidates;
- our ability to enter into strategic partnerships and the potential benefits of such partnerships;
- future results of operations and financial position and our estimates regarding expenses, capital requirements and needs for additional financing;
- our ability to raise funds needed to satisfy our capital requirements, which may depend on financial, economic and market conditions and other factors, over which we may have no or limited control;
- our financial performance;
- our and our third-party partners' and service providers' ability to continue operations and advance our therapeutic candidates through clinical trials, as well as the ability of our third party manufacturers to provide the required raw materials, antibodies and other biologics for our preclinical research and clinical trials, in light of the current market conditions or any pandemics, regional conflicts, sanctions, labor conditions, geopolitical events, natural disasters or extreme weather events;
- our ability to retain the continued service of our key professionals and to identify, hire and retain additional qualified professionals; and
- developments relating to our competitors and our industry

These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described in the section titled "Risk Factors" elsewhere in this Annual Report. Moreover, we operate in a very competitive and rapidly changing environment, and new risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this Annual Report may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements. In addition, statements that "we believe" and similar statements reflect our current beliefs and opinions on the relevant subject. These statements are

based upon information available to us as of the date of this Annual Report, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements.

You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur. We undertake no obligation to update publicly any forward-looking statements for any reason after the date of this Annual Report to conform these statements to new information, actual results or to changes in our expectations, except as required by law.

You should read this Annual Report and the documents that we file with the Securities and Exchange Commission, or the SEC, with the understanding that our actual future results, levels of activity, performance and events and circumstances may be materially different from what we expect. All forward-looking statements are qualified in their entirety by this cautionary statement, which is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995.

This Annual Report includes trademarks, tradenames, and service marks that are the property of other organizations. Solely for convenience, trademarks and tradenames referred to in this Annual Report appear without the ® and ™ symbols, but those references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights, or that the applicable owner will not assert its rights, to these trademarks and tradenames.

Part I.

Item 1. Business.

Overview

We are a clinical-stage biopharmaceutical company with a pipeline of novel biologic therapeutic candidates, developed using our proprietary modular protein engineering platforms. We leverage our innovative protein engineering technologies and deep understanding of target biology to create therapeutic candidates with attributes and mechanisms we believe to be superior to current approaches and applicable to a range of challenging, validated targets with high potential.

Recent Developments

Separation from Former Parent

In January 2024, Inhibrx, Inc., or the Former Parent, announced its intent to effect the spin-off of INBRX-101, an optimized, recombinant alpha-1 antitrypsin, or AAT, augmentation therapy in a registrational trial for the treatment of patients with alpha-1 antitrypsin deficiency. On May 29, 2024, the Former Parent completed a distribution to holders of its shares of common stock of 92% of the issued and outstanding shares of common stock of the Company, or the Distribution. On May 30, 2024, the Former Parent completed a series of internal restructuring transactions, or the Separation.

On May 30, 2024, the Former Parent completed the merger of Art Acquisition Sub, Inc., a wholly owned subsidiary of Aventis Inc., or the Acquirer, a wholly owned subsidiary of Sanofi S.A., or Sanofi, with and into the Former Parent with the Former Parent continuing as the surviving entity. Pursuant to the merger (i) all assets and liabilities primarily related to INBRX-101, or the 101 Business, were transferred to the Acquirer; and (ii) by way of the Separation, the Company acquired the assets and liabilities and corporate infrastructure associated with its ongoing programs, INBRX-106 and ozekibart (INBRX-109), and its discovery pipeline, as well as the remaining close-out obligations related to its previously terminated program, INBRX-105.

Upon the closing, each Former Parent stockholder received: (i) $30.00 per share in cash, (ii) one contingent value right per share, representing the right to receive a contingent payment of $5.00 in cash upon the achievement of a regulatory milestone, and (iii) one SEC-registered, publicly listed, share of Inhibrx for every four shares of the Former Parent's common stock held.

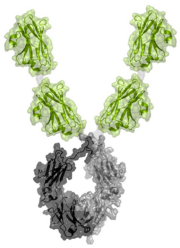
From and after the closing, Inhibrx continues to operate as a stand-alone, publicly traded company focused on its clinical programs, ozekibart (INBRX-109) and INBRX-106.

Transactions with Related Parties

We entered into a Separation and Distribution Agreement and various agreements relating to transition services, licenses, and certain other matters with the Former Parent, which govern our relationship with the Former Parent prior to, at, and after the Former Parent completed the Distribution. These agreements include the allocation of employee benefits, taxes, and certain other liabilities and obligations attributable to periods prior to, at and after the Distribution.

Current Clinical Pipeline

Our current clinical pipeline of therapeutic candidates includes ozekibart (INBRX-109) and INBRX-106, both of which utilize our multivalent formats where the precise valency can be optimized in a target-centric way to mediate what we believe to be the most appropriate agonist function:



ozekibart (INBRX-109)
Tetravalent DR5 agonist



INBRX-106
Hexavalent OX40 agonist

Program	Therapeutic Area	Target(s)/Format	STAGE OF DEVELOPMENT Preclinical	Phase 1	Phase 2	Phase 3
ozekibart (INBRX-109)*	Oncology	DR5 Tetravalent Agonist				
INBRX-106**	Oncology	OX40 Hexavalent Agonist				

* Currently being investigated in chondrosarcoma, Ewing sarcoma, and colorectal cancer.
** Currently being investigated in patients with non-small cell lung cancer, or NSCLC, and head and neck squamous cell carcinoma, or HNSCC.

Our Leadership Team

We have assembled a team with deep scientific, manufacturing, and clinical experience in discovering and developing protein therapeutics, as well as an accomplished commercial team with the expertise we believe to successfully bring our therapeutic candidates, if approved, to market. Our in-house capabilities span the disciplines of discovery, protein engineering, cell biology, translational research, chemistry, manufacturing and controls, or CMC, clinical development, and commercialization. Members of our team bring experience from multiple organizations including Genentech, Inc., Gilead Sciences, Inc., Merck & Co., Novartis AG, Pfizer Inc., and Roche. Our board of directors is comprised of individuals with proven business and scientific accomplishments and significant operating knowledge of our company.

Our Strategy

Our mission is to discover and develop effective biologic treatments for people with life-threatening conditions and to evolve the Company into a biopharmaceutical company with a differentiated and sustainable product portfolio by focusing on the following:

Rapidly advance and optimize the clinical development of our lead programs.

Both of our clinical stage programs have key data or milestone events expected in 2025. Since entering the clinic, we have made great strides in our trials for both programs.

Apply our protein engineering platforms to create differentiated, next-generation therapeutics in focused disease areas with particular emphasis on oncology.
We continue to focus our internal clinical development where we believe we can create effective and flexible solutions to address the challenges of validated targets in areas with a high unmet medical need. Our modular protein engineering platforms enable us to efficiently identify optional therapeutic formats customized to the target biology.

Maintain our culture of innovation, execution and efficiency.
We have successfully built an innovative culture that encourages scientific risk-taking within the bounds of our data-driven philosophy. This enables our research and development team to discover numerous promising preclinical candidates cost effectively, from which we select what we believe are highly differentiated programs for clinical development.

Maximize the potential of our therapeutic pipeline.
We have a disciplined strategy to maximize the potential of our therapeutic pipeline in order to bring the greatest value to our stockholders and the most significant impact to patients. We are continuously looking to streamline operations to increase efficiency and to ensure maximum value is achieved with the capital we raise. Additionally, we will enter into strategic partnerships and transactions in instances where we believe partnering will accelerate our development timelines and/or maximize the commercial potential of any approved therapeutic candidate.

Our Pipeline

ozekibart (INBRX-109)
Ozekibart was originally known as INBRX-109, but was granted the "ozekibart" generic name in 2023 by both International Nonproprietary Names, or INN, and United States Adopted Names, or USAN. Ozekibart (INBRX-109) is a precisely engineered tetravalent therapeutic candidate targeting death-receptor 5, or DR5, a TNFRSF member, also known as tumor necrosis factor-related apoptosis-inducing ligand, or TRAIL, receptor 2. DR5 activation induces cancer-specific programmed cell death. The valency of ozekibart (INBRX-109) was selected to maximize the therapeutic index.

Background on DR5
Apoptosis is a critical process for maintaining healthy tissue homeostasis, but this process is frequently altered in cancer patients leading to the accumulation of malignant cells. Apoptotic signaling pathways are tightly regulated by the balance of pro- and anti-apoptotic factors, and their therapeutic modulation has the potential to be exploited for the treatment of cancer. Targeting the anti-apoptotic proteins has been a clinically successful strategy. For example, Venetoclax, an inhibitor of B-cell lymphoma 2, or Bcl-2, was approved by the FDA for the treatment of chronic lymphocytic leukemia in 2016.

Alternatively, we believe therapeutically targeting pro-apoptotic proteins such as DR5 is a promising oncology treatment strategy. DR5 signaling is induced by clustering of multiple receptors, which initiates an apoptotic signaling pathway resulting in cell death. The strength of apoptotic signaling is proportional to the degree of DR5 clustering. Importantly, although DR5 is expressed throughout the body, cancer cells have been shown to be more sensitive to DR5 signaling compared to healthy cells of normal tissues.

The promise of inducing cancer-specific cell death has led to extensive efforts by pharmaceutical and biotechnology companies to therapeutically exploit the DR5 pathway for the treatment of cancer. These initial efforts centered around developing recombinant versions of the DR5 ligand, TRAIL, and agonistic bivalent DR5 antibodies. Despite demonstrated clinical safety as single agents and in combination with chemotherapies, these first generation DR5 agonists failed to meet clinical efficacy endpoints. We believe these failures were caused by insufficient clustering of DR5, which is necessary for activation of this pathway.

Unmet Medical Need
We are currently investigating ozekibart (INBRX-109) in chondrosarcoma, Ewing sarcoma, and colorectal cancer. These are some of the most aggressive diseases, some of which are also orphan oncology indications that have

shown signs of activity in preclinical studies. These indications and many of these cancer subtypes do not respond well to currently approved therapies and represent a significant unmet need.

Chondrosarcoma is a rare malignant bone tumor composed of cartilage matrix-producing cells. It is reported to be the second most common primary bone sarcoma with an incidence of 1 in 200,000 per year globally. The incidence in the United States is reported to be about 1,400 cases per year. There is currently no approved systemic treatment for patients with unresectable or metastatic disease.

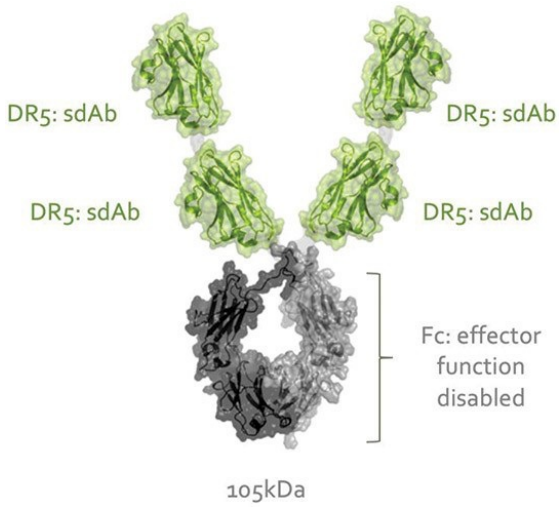
Ewing sarcoma is a rare type of cancer that occurs in bones or in the soft tissue around the bones and is more commonly found in children. The incidence of Ewing sarcoma for all ages is approximately 1.3 cases per 1 million people in the U.S., corresponding to approximately 430 new patients diagnosed per year in the U.S. The median age at diagnosis of patients with Ewing sarcoma is 15. Current treatment for Ewing sarcoma typically includes a combination of chemotherapy, surgery, and/or radiation therapy. Despite aggressive treatment, outcomes remain poor for patients with metastatic or relapsed disease, with five-year survival rates dropping below 30% in these cases, highlighting the need for more efficacious options.

Colorectal adenocarcinoma, or CRC, is the third most frequent cancer globally and the second leading cause of cancer-related death. According to the WHO, there were nearly 2,000,000 new cases of CRC in 2020, with nearly 1,000,000 deaths. Effective therapies beyond the second-line setting are limited. In the U.S., the five-year relative survival rate in patients with metastatic CRC is 15.7%, underscoring the need for better treatments.

Our Solution — ozekibart (INBRX-109)

Ozekibart (INBRX-109) is a tetravalent agonist of DR5 that we designed with our proprietary single domain antibody, or sdAb, platform to drive cancer-selective programmed cell death and to maximize potency while minimizing on-target liver toxicity arising from hepatocyte apoptosis. We believe ozekibart (INBRX-109) has the potential to overcome the limitations of previous DR5 agonists. As shown in the diagram below, ozekibart (INBRX-109) is comprised of four DR5 targeted sdAbs fused to an Fc region that has been modified to prevent Fc receptor interactions. In preclinical studies, we have observed that ozekibart (INBRX-109) has the ability to potently agonize DR5 through efficient receptor clustering, causing cancer cell death. Based upon experience with earlier generation DR5 agonists, hepatocytes appear to be a non-cancerous cell type particularly sensitive to DR5 agonism. We have engineered ozekibart (INBRX-109) with our proprietary sdAb modifications to reduce recognition by pre-existing anti-drug antibodies in humans, which can lessen the potential for hyper-clustering and thereby reduce potential hepatotoxicity.

ozekibart (INBRX-109): Tetravalent DR5 Agonistic Antibody



Phase 1 Clinical Trial of ozekibart (INBRX-109)

We initiated a Phase 1 clinical trial in the United States in November 2018. This Phase 1 clinical trial is designed as an open-label, three-part trial in patients with locally advanced or metastatic solid tumors. Primary objectives of the Phase 1 trial are safety, tolerability, and determination of the maximum tolerated dose, or MTD, and recommended Phase 2 dose. For some of the expansion cohorts in part 2 and part 3, clinical anti-tumor efficacy, such as response rate, was also included as one of the primary objectives. Secondary objectives are serum exposure and immunogenicity, as measured by frequency of anti-drug antibodies. Exploratory objectives include clinical anti-tumor efficacy, based on response rate, duration of response, disease control rate, progression-free survival and overall survival, as well as evaluation of potential predictive diagnostic and pharmacodynamic biomarkers.

Part 1

Part 1 of the trial utilized a traditional 3+3 dose escalation design escalating ozekibart (INBRX-109) as a single agent from 0.3 mg/kg to 30 mg/kg. Twenty patients were enrolled in this portion of the trial, which was completed in August 2019. Ozekibart (INBRX-109) was observed to be well-tolerated without significant toxicities observed at doses up to and including the maximum administered dose of 30 mg/kg. No MTD was reached.

Part 2

In September 2019, we commenced single agent dose expansion cohorts. Part 2 is now complete and enrolled 116 patients in single agent dose cohorts in the following tumor types: colorectal and gastric adenocarcinomas, malignant pleural mesothelioma, chondrosarcoma, synovial sarcoma, and solid tumors.

Part 3

In February 2021, we initiated chemotherapy combination cohorts in Part 3 of this trial. We are currently investigating ozekibart (INBRX-109) in Ewing sarcoma, colorectal adenocarcinoma, and chondrosarcoma in Part 3 of this trial.

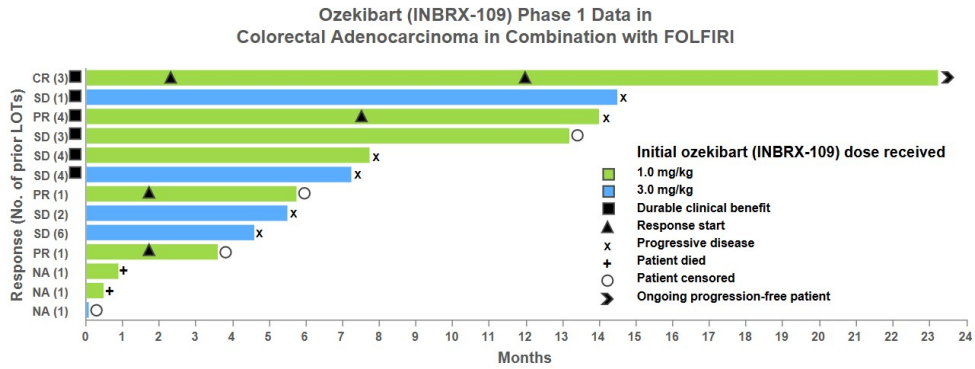
Interim Results from the Phase 1 cohort in Ewing Sarcoma

In November 2023, we announced interim efficacy and safety data from the cohort of the Phase 1 trial evaluating ozekibart (INBRX-109) in combination with Irinotecan, or IRI, and Temozolomide, or TMZ, for the treatment of advanced or metastatic, unresectable Ewing sarcoma. Among the 13 patients evaluable as of the data cut of September 8, 2023, the observed disease control rate was 76.9%, or 10 out of 13 patients as measured by

RECISTv1.1, with seven patients achieving partial responses (53.8%) and three patients achieving stable disease (23.1%). Overall, ozekibart (INBRX-109) in combination with IRI/TMZ was well-tolerated from a safety perspective. We have expanded recruitment of this cohort by 50 patients as a result of these preliminary findings and expect to have interim data during the second half of 2025.

Interim Results from the Phase 1 cohort in Colorectal Adenocarcinoma

In January 2025, we announced interim efficacy and safety data from the cohort of the Phase 1 trial evaluating ozekibart (INBRX-109) in combination with FOLFIRI for the treatment of advanced or metastatic, unresectable colorectal adenocarcinoma, or CRC. Efficacy was assessed in 10 of the 13 patients who received at least one dose of ozekibart, based on RECIST v1.1 criteria. Interim results as of the cutoff date of December 2, 2024 demonstrated one complete response, or CR, three partial responses, or PR, and six cases of stable disease, or SD. Durable disease control lasting ≥180 days was observed in 46.2% of patients, with a median progression-free survival of 7.85 months. All patients had received at least one prior line of systemic therapy (median: two; range: 1–6). Notably, the patient achieving a CR had undergone three prior lines of therapy, and two PRs occurred in patients who had failed prior FOLFIRI-based treatments. Ozekibart-related treatment-emergent adverse events, or TEAEs, were reported in 84.6% of patients, with most being grade 1 or 2 in severity. Grade ≥3 TEAEs were observed in 30.8% of patients. The most common ozekibart-related TEAEs included nausea, increased alanine aminotransferase, diarrhea, and fatigue, with the majority being low-grade.



n=13

ORR, n (%)	4 (30.8)
CR, n (%)	1 (7.7)
PR, n (%)	3 (23.1)
SD, n (%)	6 (46.2)
DCR, n (%)	10 (76.9)

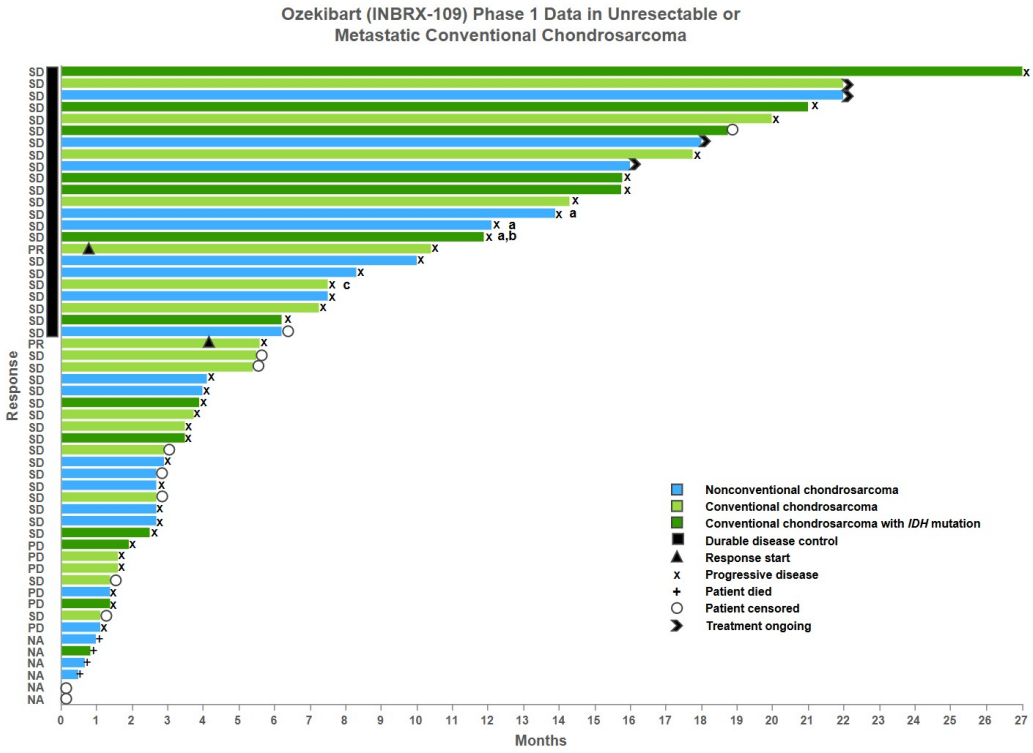
We have expanded recruitment of this cohort by 50 patients as a result of these preliminary findings in order to validate these findings in a more uniform patient population. The cohort is expected to enroll up to 50 patients, each with two to three prior lines of systemic therapy, and data are anticipated in the third quarter of 2025.

Interim Results from the Phase 1 cohort in Chondrosarcoma

In January 2021, the FDA granted Fast Track designation to ozekibart (INBRX-109) for the treatment of patients with unresectable or metastatic conventional chondrosarcoma. In November 2021, the FDA granted orphan drug designation for ozekibart (INBRX-109) for the treatment of chondrosarcoma. In August 2022, the European Commission granted orphan designation for ozekibart (INBRX-109) for the treatment of chondrosarcoma.

In November 2024, we announced interim efficacy and safety data from the ongoing Phase 1 expansion cohort evaluating ozekibart (INBRX-109) for the treatment of chondrosarcoma. Among the 31 patients evaluable as of

August 9, 2024, the observed disease control rate was 77.8%, or 42 out of 54 patients as measured by RECISTv1.1, with two patients achieving partial responses (3.7%) and 40 patients achieving stable disease (74.1%). Disease control was observed in patients with and without IDH1/IDH2 mutations. Of those achieving stable disease, 55.0% had decreases from baseline in tumor size. 23 of 42 patients (54.8%) who achieved disease control maintained control for longer than 6 months, and the longest duration of stable disease observed was 27 months. At the time of evaluation, the median progression-free survival, or PFS, was 7.42 months, and one patient remained on study.



Data cutoff: August 9, 2024; presented at the CTOS Annual Meeting, November 13-16, 2024, San Diego, CA

a. Patient continued receiving ozekibart beyond progression.

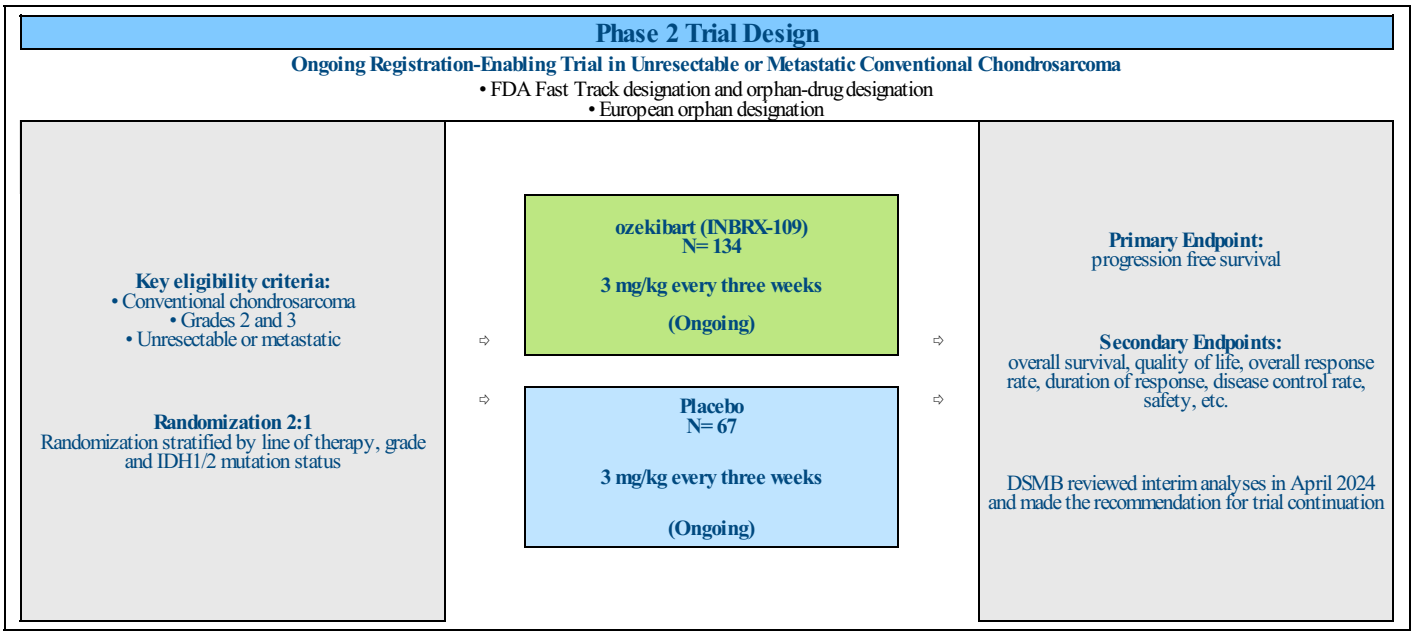
b. Patient received priming dose of ozekibart 0.3 mg/kg in cycle 1; in all subsequent cycles, the patient received 3 mg/kg.

c. Patient received ozekibart at a dose of 10 mg/kg.

	n=54
ORR, n (%)	2 (3.7)
DCR, n (%)	42 (77.8)
PR, n (%)	2 (3.7)
SD, n (%)	40 (74.1)

Phase 2 ozekibart (INBRX-109) in Chondrosarcoma

In June 2021, we initiated a Phase 2 trial in patients with metastatic conventional chondrosarcoma, which will enroll approximately 200 patients in total at 50 different sites worldwide. Primary objectives of the ongoing Phase 2 trial are to evaluate the efficacy of ozekibart (INBRX-109) as measured by median PFS, assessed by central real-time independent radiology review. Secondary objectives are to evaluate the overall survival, median PFS by investigator assessment, quality of life, objective response rate, duration of response, disease control rate, safety and tolerability, pharmacokinetics and anti-drug antibodies to ozekibart (INBRX-109).



In early 2023, the Phase 2 trial was placed on partial clinical hold by the FDA, and we paused patient enrollment in the trial following the occurrence of a fatal (grade 5) serious adverse event of hepatotoxicity (or hepatic failure) event triggering the predefined stopping rules built into the protocol. The additional insight gained on patients at risk of significant hepatotoxicity led us to believe that elderly patients with fatty liver disease are the at higher-risk population. We implemented the Hepatic Steatosis Index, or HSI, into the protocol and excluded those higher-risk elderly patients with an HSI score of 36 or higher, which has helped to mitigate the risk of severe hepatotoxicity. The FDA lifted the hold in April 2023 after we amended the trial protocol.

The safety and integrity of the Phase 2 trial is overseen by an independent group of qualified experts, known as a data safety monitoring board, or DSMB, committee. This group provides the recommendation of whether a trial may move forward at designated check points based on access that only the group maintains to available data from the trial. Suspension or termination of development occurs if it is determined that the participants or patients are being exposed to an unacceptable health risk. In April 2024, the DSMB committee reviewed the interim analyses for the Phase 2 trial and made the recommendation that we continue forward with the current trial. We expect to announce data from this trial around the third quarter of 2025.

Safety Data for ozekibart (INBRX-109)

Of the 238 patients studied and evaluable in our Phase 1 trial as of the cutoff date of January 3, 2025, the treatment-related serious adverse events observed were (i) abnormal laboratory findings of increased alanine aminotransferase (6 or 2.5%), increased aspartate aminotransferase (6 or 2.5%), transaminases increased, an increased on hepatic enzyme (1 or 0.4%), increased liver function test (1 or 0.4%) and decreased platelet count (1 or 0.4%), (ii) gastrointestinal disorders, which consisted of diarrhea (4 or 1.7%), enterocolitis, an inflammation of the small intestine and colon (1 or 0.4%), colitis (1 or 0.4%), nausea (1 or 0.4%) and vomiting (1 or 0.4%), (iii) blood and lymphatic system disorders, which consisted of anemia (3 or 1.3%), febrile neutropenia, a condition where the body has a reduced number of a certain type of white blood cells in conjunction with a fever (2 or 0.8%) and thrombocytopenia, a condition where the number of platelets in the blood is abnormally low (1 or 0.4%), (iv) hepatobiliary (liver, bile duct or gallbladder) disorders which consisted of acute hepatic failure (3 or 1.3%), hepatic

failure (1 or 0.4%), drug-induced liver injury (1 or 0.4%), (v) general disorders and administration site conditions, which consisted of asthenia, or physical weakness or general lack of energy (1 or 0.4%) and influenza-like illness (1 or 0.4%), (vi) infections, which consisted of neutropenic sepsis, a significant inflammatory response to a presumed infection in a person with or without fever (1 or 0.4%) and sepsis, an overreactive and extreme inflammatory response to infection (1 or 0.4%), (vii) metabolism and nutrition disorders, which consisted of dehydration (1 or 0.4%), failure to thrive (1 or 0.4%) and hyponatremia, a condition where the sodium levels in blood are lower than normal (1 or 0.4%), (viii) tachycardia (1 or 0.4%), and (ix) posterior reversible encephalopathy syndrome, a condition marked by headaches, vision problems, mental changes, seizures, and swelling in the brain (1 or 0.4%).

Of 161 patients studied and evaluable in our Phase 2 trial as of the cutoff date of January 3, 2025, the serious adverse events related to study drug (ozekibart (INBRX-109) or placebo) were (i) abnormal laboratory findings of increased alanine aminotransferase (5 or 3.1%) and increased aspartate aminotransferase (5 or 3.1%), (ii) hepatobiliary disorders, which consisted of hypertransaminasemia (2 or 1.2%) and hepatic failure (2 or 1.2%), (iii) infections which consisted of infectious enterocolitis (1 or 0.6%), (iv) muscular weakness (1 or 0.6%), (v) cardiac disorders which consisted of angina pectoris (1 or 0.6%) and (vi) renal and urinary disorders, which consisted of hemorrhagic Cystitis, a condition in which the bladder becomes inflamed and starts to bleed (1 or 0.6%).

INBRX-106

INBRX-106 is a hexavalent OX40 agonist, currently being investigated as a single agent and in combination with KEYTRUDA® (pembrolizumab), a PD-1 blocking checkpoint inhibitor, in patients with locally advanced or metastatic solid tumors. KEYTRUDA® is a registered trademark of Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc., Rahway, NJ, USA.

Background on Immunotherapy

A notable recent success in cancer treatment is the approval of checkpoint inhibitor immunotherapies as therapeutic agents. Immune checkpoints are key mechanisms that fine-tune and control the body's immune response. In the cancer setting, tumors have developed strategies for hijacking these checkpoints, preventing an immune response to the cancer and allowing the tumor cells to proliferate unchecked. Checkpoint inhibitor immunotherapies were developed to overcome this phenomenon by relieving immune cell inhibition, resulting in a potentially long-lasting amplification of the anti-tumor immune response. Therapies against checkpoint proteins, such as PD-1 and PD-L1, produced impressive results in clinical development, resulting in marketing approvals in a number of malignancies.

Background on OX40

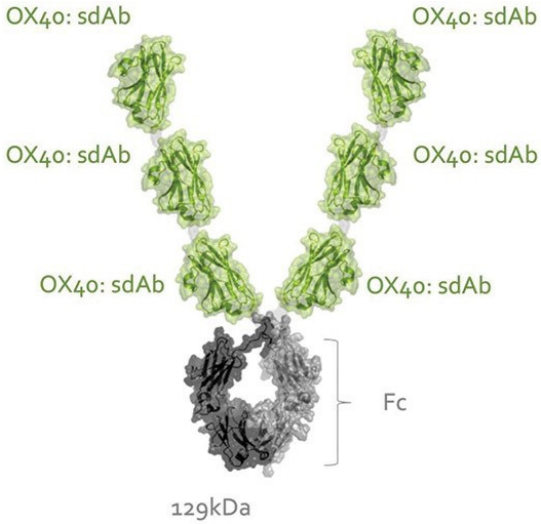
OX40, a member of the TNFRSF, is predominately expressed and is a key co-stimulatory receptor on activated T-cells. Signaling through OX40 provides co-stimulation that promotes T-cell expansion, enhanced effector function and memory cell formation, and prevents activation-induced cell death. The natural mechanism of OX40 activation is via the interaction with its trimeric ligand, OX40L, which serves to effectively cluster multiple OX40 molecules and facilitate downstream signaling leading to nuclear factor kappa-light-chain-enhancer of activated B cells, or NFkB, activation. Based on the capacity for OX40 signaling to enhance anti-tumor immunity in preclinical studies, there have been many efforts to therapeutically exploit this pathway for cancer immunotherapy. Most previously developed agents were bivalent OX40 agonists, the configuration of which we believe to be poorly suited for efficient receptor clustering, evidenced by the lack of clinical responses observed for such molecules.

Unmet Medical Need

Despite unprecedented clinical response rates, the majority of patients fail to respond to therapies targeting PD-1 and PD-L1. We believe this is in part because T-cells require co-stimulation for full functionality. Thus, checkpoint inhibition alone is likely insufficient to fully enable the immune system to attack a tumor, and we believe further benefit could be derived by the addition of immune co-stimulatory agents.

Our Solution

INBRX-106 is a precisely engineered hexavalent sdAb-based therapeutic candidate targeting OX40, designed to be an optimized agonist of this co-stimulatory receptor. As shown in the diagram below, INBRX-106 is composed of six OX40 targeting sdAbs and a functional Fc domain.



As a hexavalent therapeutic candidate, INBRX-106 is designed to bind six OX40 molecules on the cell surface to mediate efficient receptor clustering and downstream signaling. In preclinical studies, we observed that INBRX-106 elicited superior OX40 agonism when compared to the bivalent antibodies, 1A7 (analog of MOXR-0916) or 1D10 using an OX40 expressing NFkB reporter cell line, wherein clustering of OX40 receptor mediated signaling culminated in luciferase expression. We also observed that INBRX-106 can mediate T-cell co-stimulation and reduce the suppressive activity of regulatory T-cells. Additionally, INBRX-106 is able to exploit IgG-mediated effector function via the Fc domain.

Clinical Data

We initiated a Phase 1/2 clinical trial in December 2019 for INBRX-106. This trial is designed as an open-label, four-part trial in patients with locally advanced or metastatic solid tumors. Primary objectives of the trial are safety and tolerability, and the determination of the MTD and recommended Phase 2 dose of INBRX-106 as a single agent and in combination with Keytruda. For some of the expansion cohorts in part 4, clinical anti-tumor efficacy, such as response rate, was also included as one of the primary objectives. Secondary objectives are serum exposure, immunogenicity, as measured by the frequency of anti-drug antibodies, and clinical anti-tumor efficacy per RECIST (version 1.1) and immune RECIST based on response rate, duration of response, disease control rate, progression-free survival and overall survival. Exploratory objectives will include evaluation of potential predictive diagnostic and pharmacodynamic biomarkers.

Part 1 of the trial utilized a traditional 3+3 algorithm for single agent dose escalation from 0.0003 mg/kg to 3 mg/kg in twenty patients. INBRX-106 was observed to be generally well tolerated in humans. The most common adverse events, or AEs, reported for INBRX-106 were Grade 1 and 2 and notably, cutaneous toxicities, which are common immune-related AEs associated with immune checkpoint inhibitors. These AEs, which were mostly mild or moderate non-serious adverse events and likely immune-related toxicities were in line with the mechanism of action of this candidate therapeutic. The maximum administered dose was 3 mg/kg and the MTD level was not reached.

Part 2 of the trial, single agent dose expansion, administered INBRX-106 in different dosing schedules to patients with tumor types responsive to checkpoint inhibitors. Part 2 treatment cohorts of this trial were in the following tumor types: NSCLC, melanoma, HNSCC, gastric or gastroesophageal junction adenocarcinoma, renal cell carcinoma, and urothelial (transitional) cell carcinoma.

In Parts 3 and 4 of this trial, INBRX-106 is being evaluated in combination with Keytruda. In the all-comer Part 3 of the trial, INBRX-106 was escalated in combination with Keytruda and enrolled patients with locally advanced or

metastatic solid tumors. It was observed to be well tolerated, with predominantly mild or moderate non-serious immune-related toxicities noted. We observed durable responses across multiple tumor types.

In Part 4, INBRX-106 combination expansion cohorts, we continue to enroll patients with NSCLC and HNSCC, both in combination with Keytruda. The patients must be positive for PD-L1 expression, as determined by immunohistochemistry, and possess adequate hematologic and organ function, to qualify for enrollment. As of the January 3, 2025 cutoff date, it has been observed to be well tolerated, with predominantly mild or moderate non-serious immune-related toxicities noted.

The initial data observed from 24 NSCLC patients who all had previous checkpoint inhibitor exposure was tumor reduction or stabilization of target lesions in more than half the patients. Of those patients, one complete response and four partial responses were observed. The initial data observed from 14 HNSCC patients, seven of which were checkpoint failures and seven of which were checkpoint naive, was tumor reduction of target lesions in half the patients. Of those patients, two complete responses and five partial responses were observed. These cohorts have been expanded to recruit additional patients, and a new cohort was added in NSCLC patients with any PD-L1 status to evaluate the safety of chemotherapy when used in conjunction with the INBRX-106 and Keytruda combination. All of these cohorts are currently recruiting, and we expect to have a more mature dataset in the fourth quarter of 2025 and plan to provide an update at that time.

In June 2024, a seamless Phase 2/3 clinical trial was initiated for INBRX-106 in combination with Keytruda as a first-line treatment for patients with locally advanced recurrent or metastatic head and neck cancer, or HNSCC. This trial will recruit patients who have not received prior checkpoint inhibitors and whose tumors express a PDL-1 combined positive score, or CPS, equal to or greater than 20. We plan to enroll approximately 60 patients in the Phase 2 portion with a primary endpoint of overall response rate, or ORR, supported by secondary endpoints of duration of response, PFS, and safety. The Phase 3 portion, pending receipt of the Phase 2 data, will be approximately 350 patients randomized to INBRX-106 or placebo in combination with Keytruda. The primary endpoint for the Phase 3 portion of the study will be PFS and overall survival. We expect to announce data from the Phase 2 portion of this trial in the fourth quarter of 2025.

Safety Data for INBRX-106

Of the 213 patients studied and evaluable in our Phase 1/2 clinical trial for INBRX-106 as of the cutoff date of January 3, 2025, the treatment-related serious adverse events observed were (i) general disorders and administration site conditions, which consisted of pyrexia, or fever (4 or 1.9%), systemic inflammatory response syndrome (1 or 0.5%), and influenza-like illness (1 or 0.5%), (ii) metabolism and nutrition disorders, which consisted of failure to thrive (1 or 0.5%), hyponatremia, a condition when the sodium levels in blood are lower than normal (1 or 0.5%), and hypercalcemia, a condition when the calcium levels in blood are higher than normal (1 or 0.5%), (iii) gastrointestinal disorders, which consisted of diarrhea (3 or 1.4%), gastritis (1 or 0.5%), colitis (1 or 0.5%), immune-mediated enterocolitis (1 or 0.5%), and vomiting (1 or 0.5%), (iv) blood and lymphatic system disorders, which consisted of anemia (1 or 0.5%) and pancytopenia, a condition in which there is lower-than-normal number of red and white blood cells and platelets in the blood (1 or 0.5%), (v) cardiac disorders, which consisted of acute myocardial infarction (1 or 0.5%), immune-mediated myocarditis (1 or 0.5%), myocarditis (1 or 0.5%), and tachycardia (1 or 0.5%), (vi) cytokine release syndrome (3 or 1.4%), (vii) infusion-related reactions (2 or 0.9%), (viii) primary adrenal insufficiency (1 or 0.5%), (ix) increased blood bilirubin (1 or 0.5%), (x) myositis, or inflamed muscles (1 or 0.5%), (xi) toxic encephalopathy, or brain dysfunction caused by toxic exposure (1 or 0.5%), (xii) acute kidney injury (1 or 0.5%), (xiii) delirium (1 or 0.5%), (xiv) dyspnea (1 or 0.5%), (xv) drug eruption, a skin rash caused by medication (1 or 0.5%), and (xvi) pneumonia (2 or 0.9%).

Intellectual Property

We strive to protect the proprietary technology and information commercially or strategically important to our business. We seek to obtain and maintain, patent rights intended to cover the technologies incorporated into, or used to produce, our therapeutic candidates, the compositions of matter of our therapeutic candidates and their methods of use and manufacture, as well as other inventions that are important to our business. We also seek to obtain strategic or commercially valuable patent rights in the United States and other jurisdictions.

As of December 31, 2024, our patent estate contains 35 patent families that we solely own, 2 patent families that we co-own with Regeneron Pharmaceuticals, Inc. (formerly 2Seventy Bio, Inc.) and 2 patent families that we co-own with Phylaxis BioScience, LLC. The patent estate is comprised of 23 issued U.S. patents, 194 issued foreign patents in various countries around the world, including Australia, Canada, China, Europe (validated in France, Germany, Italy, Spain, the United Kingdom and other European countries), Russia, India, Israel, Japan, Mexico, New Zealand, Singapore, South Korea, South Africa and other countries as further described below, 36 pending U.S. patent applications, 3 pending Patent Cooperation Treaty, or PCT, applications and 420 pending patent applications in various jurisdictions outside of the U.S., as further described below.

INBRX-106

With regard to INBRX-106, as of December 31, 2024, we solely own 3 patent families relating to the composition of matter of INBRX-106, its methods of use for the treatment of cancer and/or its alternative dosing regimens for the treatment of cancer. These patent families are comprised of: 2 issued U.S. patents, 10 issued patents in various countries around the world, including Australia, Indonesia, Israel, Japan, Mexico, Russia and Singapore, 2 pending U.S. patent applications, 1 pending PCT application and 42 pending patent applications in various countries around the world, including Argentina, Australia, Brazil, Canada, China, Europe, Gulf Cooperation Council, India, Indonesia, Israel, Japan, Malaysia, Mexico, New Zealand, Philippines, Russia, Singapore, South Africa, South Korea, Taiwan, Thailand and Vietnam. These patents and patents issuing from these applications, if any, are expected to expire between 2037 and 2043, absent any patent term adjustments or extensions or terminal disclaimers.

INBRX-109

With regard to ozekibart (INBRX-109), as of December 31, 2024, we solely own 4 patent families relating to the composition of matter of INBRX-109, its methods of use for the treatment of cancer, its formulations, and/or its use in combination with select compounds. These patent families are comprised of: 3 issued U.S. patents, 49 issued patents in various countries around the world, including Australia, China, Europe (validated in France, Germany, Italy, Spain, the United Kingdom and other European countries), India, Indonesia, Israel, Japan, Mexico, Russia, Singapore and South Africa, 4 pending U.S. patent applications and 63 pending patent applications in various countries around the world, including Australia, Brazil, Canada, China, Eurasia, Europe, Indonesia, India, Israel, Japan, Mexico, New Zealand, Russia, Singapore, South Africa, South Korea, Taiwan and Thailand. These patents and patents issuing from these applications, if any, are expected to expire between 2036 and 2043, absent any patent term adjustments or extensions or terminal disclaimers.

Single Domain Antibody and Multispecific Technologies

With regard to our single domain antibody and multispecific technologies, as of December 31, 2024, we solely own 6 patent families relating to non-immunogenic single domain antibodies, multispecific molecules having a constrained CD3 binding, molecules comprising modified IL-2 variants, and/or methods of using such molecules to treat diseases (e.g., cancer). These patent families are comprised of: 2 issued U.S. patents, 12 issued patents in Australia, Canada, India, Japan, Malaysia, Mexico, New Zealand, Russia and South Korea, 7 pending U.S. patent applications and 90 pending patent applications in various countries around the world, including Argentina, Australia, Brazil, Canada, China, Europe, Gulf Cooperation Council, India, Israel, Japan, Malaysia, Mexico, New Zealand, Philippines, Russia, Saudi Arabia, Singapore, South Africa, South Korea and Taiwan. These patents and patents issuing from these applications, if any, are expected to expire between 2036 and 2041, absent any patent term adjustments or extensions or terminal disclaimers.

We continually assess and refine our intellectual property strategy as we develop new technologies and therapeutic candidates. As our business evolves, we may, among other activities, file additional patent applications in pursuit of our intellectual property strategy, to adapt to competition or to seize potential opportunities.

The term of individual patents depends upon the laws of 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 of a non-provisional patent application. However, the term of United States patents may be extended for delays incurred due to compliance with the FDA requirements or by delays encountered during prosecution that are caused by the USPTO. For example, the Hatch-Waxman Act permits a patent term extension for FDA-approved drugs 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 extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, and only one patent applicable to an approved drug may be extended. Similar provisions are available in Europe and other jurisdictions to extend the term of a patent that covers an approved drug. In the future, if and when our therapeutic candidates receive FDA approval, we expect to apply for patent term extensions on patents covering those therapeutic candidates. We intend to seek patent term extensions in any jurisdiction where these are available and where we also have a patent that may be eligible; however, there is no guarantee that the applicable authorities, including the USPTO and FDA, will agree with our assessment of whether such extensions should be granted, and even if granted, the length of such extensions.

We also rely on trade secrets to protect aspects of our technology and business not amenable to, or that we do not consider appropriate for, patent protection. We seek to protect this intellectual property, in part, by requiring our employees, consultants, sponsored researchers and other service providers and advisors to execute confidentiality agreements upon the commencement of employment or other relationship with us. In general, these agreements provide that 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. In the case of employees, the agreements further provide that inventions and discoveries conceived or reduced to practice by the individual that are related to our business, or actual, or demonstrably anticipated, research or development, or made during normal working hours, on our premises or using our equipment, supplies, or proprietary information, are our exclusive property. In many cases our agreements with consultants, sponsored researchers and other service providers and advisors require them to assign, or grant us licenses to, inventions resulting from the work or services they render under such agreements or grant us an option to negotiate a license to use such inventions.

Further, we expect to rely on data exclusivity, market exclusivity, patent term adjustment and patent term extensions when available.

We seek trademark protection in the United States and in certain other jurisdictions where available and when we deem appropriate. We currently have a registration for "Inhibrx" in the United States and have filed trademark applications for "Inhibrx Biosciences" in the United States. We intend to file applications for trademark registrations in connection with our therapeutic candidates in various jurisdictions, including the United States.

Competition

The biopharmaceutical industry is characterized by rapid evolution of technologies, fierce competition and strong defense of intellectual property. While we believe that our platforms, technology, knowledge, experience, and scientific resources provide us with competitive advantages, we face competition from major pharmaceutical and biotechnology companies, academic institutions, governmental agencies and public and private research institutions, among others.

Any therapeutic candidates that we successfully develop and commercialize will compete with currently approved therapies and new therapies that may become available in the future. Key product features that would affect our ability to effectively compete with other therapeutics include the efficacy, safety and convenience of our therapeutics, the ease of use and effectiveness of any complementary diagnostics and/or companion diagnostics, and price and levels of reimbursement. Our primary competitors fall into the following groups:

- Companies developing novel therapeutics based on sdAb or alternative scaffold product candidates, including Alligator Bioscience AB, Crescendo Biologics Ltd., GlaxoSmithKline plc, Lava Therapeutics N.V., Molecular Partners AG, Precirix NV, and Sanofi;
- Antibody drug discovery companies that may compete with us in the search for novel therapeutic antibody targets, including Regeneron Pharmaceuticals, Inc., Adimab LLC, Genmab A/S, Macrogenics, Inc., Merus N.V., Numab Therapeutics AG, Amgen, Inc., Xencor, Inc., and Zymeworks Inc.; and
- Companies developing therapeutics for the treatment of autoimmune diseases, including Sanofi, Amgen Inc., AstraZeneca plc, F. Hoffmann-La Roche AG, Pfizer Inc., Merck & Co., Inc., Novartis AG, Candid Therapeutics, Inc., Hinge Bio, Inc., and Apogee Therapeutics, Inc.

Our competitors also include other large pharmaceutical and biotechnology companies who may be developing therapeutic candidates with mechanisms similar to or targeting the same indications as our therapeutic candidates.

The availability of reimbursement from government and other third-party payors will also significantly affect the pricing and competitiveness of our therapeutic candidates. Our competitors also may obtain FDA or other marketing approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market.

Many of the companies against which we may compete have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining marketing approvals and marketing approved products than we do. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These early stage and more established 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.

Government Regulation

Governmental authorities in the United States, at the federal, state and local level, and other countries extensively regulate, among other things, the research, development, testing, manufacture, labeling, packaging, promotion, storage, advertising, distribution, marketing and export and import of product candidates such as those we are developing. Our therapeutic candidates must be approved by the FDA through the Biologics License Application, or BLA, process before they may be legally marketed in the United States and will be subject to similar requirements in other countries prior to marketing in those countries. The process of obtaining marketing approvals in the U.S. and in foreign countries and jurisdictions, and the subsequent compliance with applicable federal, state, local and foreign statutes and regulations, require the expenditure of substantial time and financial resources. Failure to comply with the applicable FDA requirements at any time during the product development process, approval process or after approval, may subject an applicant to administrative or judicial sanctions.

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

- completion of certain preclinical laboratory tests, animal studies and formulation studies in accordance with Good Laboratory Practice, or GLP, regulations and other applicable requirements;
- submission to the FDA of an Investigational New Drug application, or IND, which must become effective before human clinical trials may begin;
- approval by an independent institutional review board, or IRB, or ethics committee at each clinical site before each trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with Good Clinical Practice regulations, or GCPs, to evaluate the safety, purity and potency, or efficacy, of the therapeutic candidate for its intended use;
- preparation and submission to the FDA of a BLA;
- 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 drug is produced to assess compliance with current Good Manufacturing Practice requirements, or cGMPs, to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity;
- satisfactory completion of potential inspection of selected clinical investigation sites to assess compliance with GCPs; and
- FDA review and approval of the BLA to permit commercial marketing of the product for particular indications for use in the United States.

Once a therapeutic candidate is identified for development, it enters the preclinical testing stage. Preclinical tests generally include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies. An IND sponsor must submit the results of the preclinical tests, together with manufacturing information and analytical data, to the FDA as part of an IND. An IND is a request for allowance from the FDA to administer an

investigational drug or biological product to humans. An IND will also include a protocol detailing, among other things, the objectives of the clinical trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated, if the trial includes an efficacy evaluation. Some preclinical testing may continue even after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, 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. Submission of an IND may therefore not result in FDA allowance to begin a clinical trial. Clinical holds also may be imposed by the FDA at any time before or during clinical trials due in response to safety concerns or due to non-compliance with specific FDA requirements.

All clinical trials must be conducted under the supervision of one or more qualified investigators in accordance with GCPs, which include, among other things, the requirement that all research subjects provide their informed consent in writing for their participation in any clinical trial. Clinical trials must be conducted under protocols detailing, among other things, the objectives of the trial, dosing procedures, subject selection and exclusion criteria and any safety and effectiveness criteria to be evaluated. Each protocol must be submitted to the FDA as part of the IND, and a separate submission to the existing IND must be made for each successive clinical trial conducted during product development and for any subsequent protocol amendments. While the IND is active, progress reports summarizing the results of the clinical trials and preclinical studies performed since the last progress report, among other information, must be submitted at least annually to the FDA, and written IND safety reports must be submitted to the FDA and investigators for serious and unexpected suspected adverse events, findings from other studies suggesting a significant risk to humans exposed to the same or similar drugs, findings from animal or in vitro testing suggesting a significant risk to humans, and any clinically important increased incidence of a serious suspected adverse reaction compared to that listed in the protocol or investigator brochure.

Furthermore, an independent IRB or ethics committee at each institution participating in the clinical trial must review and approve each protocol before a clinical trial commences at that institution and must also approve the information regarding the trial and the consent form that must be provided to each trial subject or his or her legal representative, monitor the study until completed and otherwise comply with IRB regulations. The FDA or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk or that the trial is unlikely to meet its stated objectives. 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. In addition, some clinical trials are overseen by an independent group of qualified experts organized by the sponsor, known as a data safety monitoring board or committee. Depending on its charter, this group may determine whether a trial may move forward at designated check points based on access to certain data from the trial. There are also requirements governing the reporting of ongoing clinical studies and clinical study results to public registries, including clinicaltrials.gov.

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

- Phase 1: The therapeutic candidate is initially introduced into healthy human subjects and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion and, if possible, to gain an early indication of its effectiveness.
- Phase 2: The therapeutic candidate is administered to a limited patient population with a specified disease or condition to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the therapeutic candidate for specific targeted diseases and to determine dosage tolerance and appropriate dosage.
- Phase 3: The therapeutic candidate is administered to an expanded patient population to further evaluate dosage, to provide substantial evidence of efficacy and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk-benefit ratio of the therapeutic candidate and provide an adequate basis for product labeling.

Post-approval trials, sometimes referred to as Phase 4 studies, may be conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the approved therapeutic

indication. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of approval of a BLA.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the drug and finalize a process for manufacturing the product in commercial quantities in accordance with cGMPs. The manufacturing process must be capable of consistently producing quality batches of the therapeutic candidate and, among other things, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final drug. In addition, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the therapeutic candidate does not undergo unacceptable deterioration over its shelf life.

U.S. Review and Approval Process

The results of product development, including results from preclinical and other non-clinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the chemistry of the therapeutic candidate, proposed labeling and other relevant information are submitted to the FDA as part of a BLA requesting approval to market the product. Such information can come from company-sponsored clinical studies, or from a number of alternative sources, including studies initiated and sponsored by investigators. The submission of a BLA requires payment of a substantial application user fee to the FDA, unless a waiver or exemption applies.

In addition, the Pediatric Research Equity Act, or PREA, requires a sponsor to conduct pediatric clinical trials for most drugs, for a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration. Under the PREA, BLAs and certain supplements must contain a pediatric assessment unless the sponsor has received a deferral or waiver. The required assessment must evaluate the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and support dosing and administration for each pediatric subpopulation for which the product is deemed safe and effective. The sponsor or FDA may request a deferral of pediatric clinical trials for some or all of the pediatric subpopulations. A deferral may be granted for several reasons, including a finding that the drug is ready for approval for use in adults before pediatric clinical trials are complete or that additional safety or effectiveness data needs to be collected before the pediatric clinical trials begin. The FDA must send a non-compliance letter to any sponsor that fails to submit the required assessment, keep a deferral current or fails to submit a request for approval of a pediatric formulation.

Once a BLA has been submitted, the FDA conducts a preliminary review of the application within the first 60 days after submission, before accepting it for filing, to determine whether it is sufficiently complete to permit substantive review. The FDA may refuse to file any BLA that it deems incomplete or not properly reviewable at the time of submission and may request additional information from the application sponsor. In this event, the BLA must be resubmitted with the requested information. The resubmitted application also is subject to review before the FDA accepts it for filing.

Once filed, FDA reviews a BLA to determine, among other things, whether a therapeutic candidate is safe, pure and potent and the facility in which it is manufactured, processed, packed or held meets standards designed to assure the product's continued safety, purity and potency. Under the Prescription Drug User Fee Act, or PDUFA, guidelines that are currently in effect, the FDA has a goal to complete a standard review of an original BLA within ten months after the filing date, or, if the application qualifies for priority review, within six months after the filing date.

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, that 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 a BLA, the FDA will typically inspect the facility or facilities where the product is manufactured. Additionally, before approving an NDA, the FDA may inspect one or more clinical trial sites to assure compliance with GCPs.

After the FDA evaluates a BLA and conducts any required inspections of manufacturing facilities where the investigational product and/or its drug substance will be produced, the FDA may issue an approval letter or a Complete Response Letter, or CRL. An approval letter authorizes commercial marketing of the drug with

prescribing information for specific indications. A CRL indicates that the review cycle of the application is complete, and the application will not be approved in its present form. A CRL usually describes the specific deficiencies in the BLA identified by the FDA and may require additional clinical data, including additional clinical trials, or other significant and time-consuming requirements related to clinical trials, preclinical studies or manufacturing. If a CRL is issued, the sponsor must resubmit the BLA addressing all of the deficiencies identified in the letter or withdraw the application. Even if such data and information are submitted, the FDA may decide that the resubmitted application does not satisfy the criteria for approval.

If regulatory approval of a product is granted, such approval will be granted for particular indications and may entail limitations on the indicated uses for which such product may be marketed. For example, the FDA may approve the BLA with a Risk Evaluation and Mitigation Strategy, or REMS, to ensure the benefits of the product outweigh its risks. A REMS is a safety strategy to manage a known or potential serious risk associated with a product and to enable patients to have continued access to such medicines by managing their safe use, and could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling or the development of adequate controls and specifications. The FDA may also require one or more post-market studies or surveillance programs to further assess and monitor the product's safety and effectiveness after commercialization, and may limit further marketing of the product based on the results of these post-marketing studies.

Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition, which is a disease or condition that affects fewer than 200,000 individuals in the United States or, if it affects more than 200,000 individuals in the United States, there is no reasonable expectation that the cost of developing and making the product available in the United States for this type of disease or condition will be recovered from sales of the product. Orphan designation must be requested before submitting a BLA. After the FDA grants orphan designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications –including full BLAs– to market the same drug for the same disease or condition for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity or inability to manufacture the product in sufficient quantities. The designation of such drug or biologic also entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. However, competitors, may receive approval of different products for the disease or condition for which the orphan product has exclusivity, or obtain approval for the same product but for a different disease or condition for which the orphan product has exclusivity. Orphan exclusivity also could block the approval of a competing product for seven years if a competitor obtains approval of the "same drug," as defined by the FDA, or if the active ingredient of the therapeutic candidate is determined to be contained within the competitor's product for the same disease or condition. In addition, if an orphan designated product receives marketing approval for a disease or condition broader than what is designated, it may not be entitled to orphan exclusivity.

Expedited Development and Review Programs

The FDA has a number of programs intended to expedite the development or review of a marketing application for an investigational drug or biologic. For example, the Fast Track designation program is intended to expedite or facilitate the process for developing and reviewing therapeutic candidates that meet certain criteria. Specifically, investigational biologics are eligible for Fast Track designation if they are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the specified disease or condition. The sponsor of a Fast Track therapeutic candidate has opportunities for more frequent interactions with the applicable FDA review team during product development and, once a BLA is submitted, the application may be eligible for priority review. With regard to a Fast Track candidate, the FDA may consider for review sections of the BLA on a rolling basis before the complete application is submitted, if the sponsor provides a

schedule for the submission of the sections of the BLA, the FDA agrees to accept sections of the BLA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the BLA.

A therapeutic candidate intended to treat a serious or life-threatening disease or condition may also be eligible for Breakthrough Therapy designation to expedite its development and review. A therapeutic candidate can receive Breakthrough Therapy designation if preliminary clinical evidence indicates that the therapeutic candidate, alone or in combination with one or more other drugs or biologics, may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The designation includes all of the Fast Track program features, as well as more intensive FDA interaction and guidance beginning as early as Phase 1 and an organizational commitment to expedite the development and review of the therapeutic candidate, including involvement of senior managers.

Any therapeutic candidate submitted to the FDA for approval, including a therapeutic candidate with a Fast Track designation or Breakthrough Therapy designation, may also be eligible for other types of FDA programs intended to expedite development and review, such as priority review. A BLA is eligible for priority review if the therapeutic candidate is designed to treat a serious condition, and if approved, would provide a significant improvement in safety or efficacy compared to available therapies. The FDA will attempt to direct additional resources to the evaluation of a BLA designated for priority review in an effort to expedite the review. The FDA endeavors to review applications with priority review designations within six months of the filing date as compared to ten months for review of original BLAs under its current PDUFA review goals.

In addition, depending on the design of the applicable clinical trials, a therapeutic candidate may be eligible for accelerated approval. Specifically, biologics intended to treat serious or life-threatening diseases or conditions may be eligible for accelerated approval upon a determination that the therapeutic candidate 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, 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 generally requires that a sponsor of a drug or biologic receiving accelerated approval perform adequate and well-controlled confirmatory clinical trials, and may require that such confirmatory trials be underway prior to granting accelerated approval. Drugs or biologics receiving accelerated approval may be subject to expedited withdrawal procedures if the sponsor fails to conduct the required confirmatory trials in a timely manner or if such trials fail to verify the predicted clinical benefit. In addition, the FDA requires as a condition of accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product.

Fast Track designation, Breakthrough Therapy designation, priority review, and accelerated approval do not change the standards for approval but may expedite the development or approval process. Even if a therapeutic candidate 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.

Post-approval Requirements

Any products 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, reporting of adverse experiences, periodic reporting, product sampling and distribution, and advertising and promotion of the product. After approval, most changes to the approved product, such as adding new indications, certain manufacturing changes and additional labeling claims, are subject to further FDA review and approval.

Drug and biologic manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMPs and other laws and regulations. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMPs and other aspects of regulatory compliance.

The FDA may withdraw or limit 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 revisions to the approved labeling to add new safety information; imposition of requirements for post-market studies or clinical studies to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences for non-compliance 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 untitled letters;
- clinical holds on ongoing or planned clinical studies;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of approvals;
- product seizure or detention, or refusal to permit the import or export of products;
- consent decrees, corporate integrity agreements, debarment or exclusion from federal healthcare programs;
- mandated modification of promotional materials and labeling and the issuance of corrective information;
- the issuance of safety alerts, Dear Healthcare Provider letters, press releases and other communications containing warnings or other safety information about the product; or
- injunctions or the imposition of civil or criminal penalties.

In addition, the FDA closely regulates the marketing, labeling, advertising and promotion of biological products. A sponsor can make only those claims relating to safety, potency, purity and efficacy that are approved by the FDA 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 failure to comply with these requirements may lead to enforcement action. Physicians may prescribe legally available products for uses that are not described in the product's labeling and that differ from those tested and approved by the FDA. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications on the subject of off-label use of their products.

Biosimilars and Exclusivity

The Biologics Price Competition and Innovation Act of 2009. or BPCIA, created an abbreviated approval pathway for biological products that are highly similar, or "biosimilar," to or interchangeable with an FDA-approved reference biological product. Biosimilarity, which requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency, is generally shown through analytical studies, animal studies, and a clinical study or studies. Interchangeability requires that a product is biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product in any given patient and, for products that are administered multiple times to an individual, the biologic and the reference biologic may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. A product shown to be biosimilar or interchangeable with an FDA-approved reference biological product may rely in part on the FDA's previous determination of safety and effectiveness for the reference product for approval, which can potentially reduce the cost and time required to obtain approval to market the product.

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing that applicant's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of its product. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products.

A biological product can also obtain pediatric market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods for all formulations, dosage forms, and indications of the active ingredient and to patent terms. This six-month exclusivity, which runs from the end of an existing period of non-patent regulatory exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued "Written Request" for such a study, provided that at the time pediatric exclusivity is granted there is not less than nine months of exclusivity or patent term remaining. Pediatric exclusivity does not require the sponsor to obtain approval for the applicable product in the studied pediatric indication.

FDA Approval and Regulation of Companion Diagnostics

If the safe and effective use of a therapeutic product depends on an in vitro diagnostic medical device, then the FDA generally will require approval or clearance of that diagnostic, known as an in vitro companion diagnostic device, at the same time that the FDA approves the therapeutic product. In August 2014, the FDA issued final guidance clarifying the requirements that will apply to approval of therapeutic products and in vitro companion diagnostic devices. According to the guidance, for novel drugs, an in vitro companion diagnostic device and its corresponding therapeutic should be approved or cleared contemporaneously by the FDA for the use indicated in the therapeutic product's labeling. Accordingly, if the FDA determines that an in vitro companion diagnostic device is essential to the safe and effective use of a novel therapeutic product or indication, the FDA generally will not approve the therapeutic product or new therapeutic product indication if the in vitro companion diagnostic device is not approved or cleared for that indication. Approval or clearance of the in vitro companion diagnostic device will ensure that the device has been adequately evaluated and has adequate performance characteristics in the intended population.

Under the FDCA, in vitro diagnostics, including in vitro companion diagnostic devices, are generally regulated as medical devices. In the United States, the FDCA and its implementing regulations, and other federal and state statutes and regulations govern, among other things, medical device design and development, preclinical and clinical testing, premarket clearance or approval, registration and listing, manufacturing, labeling, storage, advertising and promotion, sales and distribution, export and import, and post-market surveillance. Unless an exemption applies, diagnostic tests require marketing clearance or approval from the FDA prior to commercial distribution, and the FDA has generally required companion diagnostics for cancer therapies to obtain approval of a premarket approval, or PMA, application.

The PMA involves a rigorous premarket review during which the applicant must prepare and provide the FDA with reasonable assurance of the device's safety and effectiveness and information about the device and its components regarding, among other things, device design, manufacturing and labeling. In addition, PMAs for certain devices must generally include the results from extensive preclinical and adequate and well-controlled clinical trials to establish the safety and effectiveness of the device for each indication for which FDA approval is sought. In particular, for a diagnostic, a PMA application typically requires data regarding analytical and clinical validation studies. As part of the PMA review, the FDA will typically inspect the manufacturer's facilities for compliance with the Quality System Regulation, or QSR, which imposes elaborate testing, control, documentation and other quality assurance requirements.

PMA approval is not guaranteed, and the FDA may ultimately respond to a PMA submission with a not approvable determination based on deficiencies in the application and require additional clinical trial or other data that may be expensive and time-consuming to generate and that can substantially delay approval. If the FDA concludes that the applicable criteria have been met, the FDA will issue a PMA order for the approved indications, which can be more limited than those originally sought by the applicant. The PMA can include post-approval conditions that the FDA believes necessary to ensure the safety and effectiveness of the device, including, among other things, restrictions on labeling, promotion, sale and distribution.

After an in vitro device is authorized by the FDA and placed on the market, it remains subject to significant regulatory requirements. Medical devices may be marketed only for the uses and indications for which they are cleared or approved. Device manufacturers must also establish registration and device listings with the FDA. A medical device manufacturer's manufacturing processes and those of its suppliers are required to comply with the applicable portions of the QSR, which currently covers the methods and documentation of the design, testing,

production, processes, controls, quality assurance, labeling, packaging and shipping of medical devices. Manufacturing sites for devices also remain subject to periodic unscheduled inspections by the FDA.

Regulation Outside of the United States

In addition to regulations in the United States, we are subject to regulations of other jurisdictions governing any clinical trials and commercial sales and distribution of our therapeutic candidates. Whether or not we obtain FDA approval for a product, we must obtain approval by the comparable regulatory authorities of countries outside of the United States before we can commence clinical trials in such countries and approval of the regulators of such countries or economic areas, such as the European Union, or the EU, before we may market products in those countries or areas. The approval process and requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from place to place, and the time may be longer or shorter than that required for FDA approval.

Non-clinical Studies and Clinical Trials

Similarly to the United States, the various phases of non-clinical and clinical research in the EU are subject to significant regulatory controls.

Non-clinical studies are performed to demonstrate the health or environmental safety of new chemical or biological substances. Non-clinical (pharmaco-toxicological) studies must be conducted in compliance with the principles of good laboratory practice, or GLP, as set forth in EU Directive 2004/10/EC (unless otherwise justified for certain particular medicinal products, e.g., radio-pharmaceutical precursors for radio-labeling purposes). In particular, non-clinical studies, both in vitro and in vivo, must be planned, performed, monitored, recorded, reported and archived in accordance with the GLP principles, which define a set of rules and criteria for a quality system for the organizational process and the conditions for non-clinical studies. These GLP standards reflect the Organization for Economic Co-operation and Development requirements.

Clinical trials of medicinal products in the EU must be conducted in accordance with EU and national regulations and the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use, or ICH, guidelines on Good Clinical Practices, or GCP, as well as the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki. If the sponsor of the clinical trial is not established within the EU, it must appoint an EU entity to act as its legal representative. The sponsor must take out a clinical trial insurance policy, and in most EU member states, the sponsor is liable to provide 'no fault' compensation to any study subject injured in the clinical trial.

The regulatory landscape related to clinical trials in the EU has been subject to recent changes. The EU Clinical Trials Regulation, or CTR, which was adopted in April 2014 and repeals the EU Clinical Trials Directive, became applicable on January 31, 2022. Unlike directives, the CTR is directly applicable in all EU member states without the need for member states to further implement it into national law. The CTR notably harmonizes the assessment and supervision processes for clinical trials throughout the EU via a Clinical Trials Information System, which contains a centralized EU portal and database.

While the EU Clinical Trials Directive required a separate clinical trial application, or CTA, to be submitted in each member state in which the clinical trial takes place, to both the competent national health authority and an independent ethics committee, much like the FDA and IRB respectively, the CTR introduces a centralized process and only requires the submission of a single application for multi-center trials. The CTR allows sponsors to make a single submission to both the competent authority and an ethics committee in each member state, leading to a single decision per member state. The CTA must include, among other things, a copy of the trial protocol and an investigational medicinal product dossier containing information about the manufacture and quality of the medicinal product under investigation. The assessment procedure of the CTA has been harmonized as well, including a joint assessment by all member states concerned, and a separate assessment by each member state with respect to specific requirements related to its own territory, including ethics rules. Each member state's decision is communicated to the sponsor via the centralized EU portal. Once the CTA is approved, clinical study development may proceed.

The CTR transition period ended on January 31, 2025, and all clinical trials (and related applications) are now fully subject to the provisions of the CTR.

Medicines used in clinical trials must be manufactured in accordance with Good Manufacturing Practice, or GMP. Other national and EU-wide regulatory requirements may also apply.

Marketing Authorization

In order to market our product candidates in the EU and many other foreign jurisdictions, we must obtain separate regulatory approvals. More concretely, in the EU, medicinal product candidates can only be commercialized after obtaining a marketing authorization, or MA. To obtain regulatory approval of a product candidate under EU regulatory systems, we must submit a MA application, or MAA. The process for doing this depends, among other things, on the nature of the medicinal product. There are two types of MAs:

- The centralized procedure provides for the grant of a single MA issued by the European Commission based on the opinion of the Committee for Medicinal Products for Human Use, or CHMP, of the European Medicines Agency, or EMA, and is valid throughout the EU. The centralized procedure is compulsory for (i) medicines derived from biotechnology, (ii) designated orphan medicinal products, (iii) advanced therapy medicinal products, or ATMPs (such as gene therapy, somatic cell therapy and tissue engineered products) and (iv) those medicines with an active substance not authorized in the EU on or before May 20, 2004 indicated for the treatment of certain diseases, such as autoimmune diseases, cancer, neurodegenerative disorders or diabetes. The centralized procedure is optional for those medicines containing a new active substance not authorized in the EU on or before May 20, 2004, for products that constitute a significant therapeutic, scientific or technical innovation, or medicines to which the granting of a MA under the centralized procedure would be in the interest of patients at the EU-level.
- The decentralized procedure provides for recognition by EU national authorities of a first assessment performed by one of the member states. Under this procedure, an identical application for MA is submitted simultaneously to the national authorities of several EU member states, one of them being chosen as the "Reference Member State," and the remaining being the "Concerned Member States." The Reference Member State must prepare and send drafts of an assessment report, summary of product characteristics and the labelling and package leaflet within 120 days after receipt of a valid marketing authorization application to the Concerned Member States, which must decide within 90 days whether to recognize approval. If any Concerned Member State does not recognize the MA on the grounds of potential serious risk to public health, the disputed points are eventually referred to the European Commission, whose decision is binding on all member states. The mutual recognition procedure is similar to the decentralized procedure except that a medicine must have already received a marketing authorization in at least one of the member states, and that member state acts as the Reference Member State.

Under the centralized procedure the maximum timeframe for the evaluation of an MAA by the EMA is 210 days, excluding clock stops.

Under the above described procedures, in order to grant the MA, the EMA or the competent authorities of the EU member states make an assessment of the risk benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy. MAs have an initial duration of five years. After these five years, the authorization may be renewed on the basis of a reevaluation of the risk-benefit balance.

Data and Marketing Exclusivity

In the EU, new products authorized for marketing (i.e., reference products) generally receive eight years of data exclusivity and an additional two years of market exclusivity upon MA. If granted, the data exclusivity period prevents generic and 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 MA 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 ten years have elapsed from the initial MA of the reference product in the EU. The overall ten-year market exclusivity period can be extended to a maximum of eleven years if, during the first eight years of those ten years, the MA 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. However, there is

no guarantee that a product will be considered by the EU's regulatory authorities to be a new chemical or biological entity, and products may not qualify for data exclusivity.

Orphan Medicinal Products

The criteria for designating an "orphan medicinal product" in the EU are similar in principle to those in the United States. A medicinal product can be designated as an orphan if its sponsor can establish that: (1) the product is intended for the diagnosis, prevention or treatment of a life threatening or chronically debilitating condition (2) either (a) such condition affects not more than five in 10,000 persons in the EU when the application is made, or (b) the product, without the benefits derived from the orphan status, would not generate sufficient return in the EU to justify the necessary investment; and (3) there exists no satisfactory method of diagnosis, prevention or treatment of the condition in question that has been authorized for marketing in the EU or, if such method exists, the product will be of significant benefit to those affected by that condition.

Orphan designation must be requested before submitting an MAA. An EU orphan designation entitles a party to incentives such as reduction of fees or fee waivers, protocol assistance, and access to the centralized procedure. Upon grant of a MA, orphan medicinal products are entitled to ten years of market exclusivity for the approved indication, which means that the competent authorities cannot accept another MAA, or grant a MA, or accept an application to extend a MA for a similar medicinal product for the same indication for a period of ten years. The period of market exclusivity is extended by two years for orphan medicinal products that have also complied with an agreed pediatric investigation plan, or PIP. No extension to any supplementary protection certificate can be granted on the basis of pediatric studies for orphan indications. Orphan designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

The orphan exclusivity period may 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 which it received orphan designation, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity or where the prevalence of the condition has increased above the threshold. Additionally, MA may be granted to a similar product for the same indication at any time if (i) the second applicant can establish that its product, although similar, is safer, more effective or otherwise clinically superior; (ii) the applicant consents to a second orphan medicinal product application; or (iii) the applicant cannot supply enough orphan medicinal product.

Pediatric Development

In the EU, MAAs for new medicinal products have to include the results of studies conducted in the pediatric population, in compliance with a PIP agreed with the EMA's Pediatric Committee, or PDCO. The PIP sets out the timing and measures proposed to generate data to support a pediatric indication of the product candidate for which MA is being sought. The PDCO can grant a deferral of the obligation to implement some or all of the measures of the PIP until there are sufficient data to demonstrate the efficacy and safety of the product in adults. Further, the obligation to provide pediatric clinical trial data can be waived by the PDCO when these data are not needed or appropriate because the product is likely to be ineffective or unsafe in children, the disease or condition for which the product is intended occurs only in adult populations, or when the product does not represent a significant therapeutic benefit over existing treatments for pediatric patients. Once the MA is obtained in all the EU member states and study results are included in the product information, even when negative, the product is eligible for six months' supplementary protection certificate extension (if any is in effect at the time of approval) or, in the case of orphan medicinal products, a two year extension of the orphan market exclusivity is granted.

Failure to comply with EU and member state laws that apply to the conduct of clinical trials, manufacturing approval, MA of medicinal products and marketing of such products, both before and after grant of the MA, manufacturing of pharmaceutical products, statutory health insurance, bribery and anti-corruption or with other applicable regulatory requirements may result in administrative, civil or criminal penalties. These penalties could include delays or refusal to authorize the conduct of clinical trials, or to grant MA, product withdrawals and recalls, product seizures, suspension, withdrawal or variation of the MA, total or partial suspension of production, distribution, manufacturing or clinical trials, operating restrictions, injunctions, suspension of licenses, fines and criminal penalties.

Regulatory Framework in the United Kingdom

On January 31, 2020, the United Kingdom formally withdrew from the EU, also known as Brexit. The United Kingdom and the EU entered into a trade agreement known as the Trade and Cooperation Agreement, which went into effect on January 1, 2021. As of January 1, 2021, the Medicines and Healthcare products Regulatory Agency, or MHRA, is the United Kingdom's standalone medicines regulatory body. As a result of the Northern Ireland Protocol, different rules applied in Northern Ireland than in Great Britain (England, Wales, and Scotland); broadly, Northern Ireland continued to follow the EU regulatory regime. However, a new arrangement called "the Windsor Framework" went into effect on January 1, 2025 and has changed the existing system under the Northern Ireland Protocol, including the regulation of pharmaceutical products in the United Kingdom. Specifically, the MHRA is now responsible for approving all medicines intended to be marketed in the United Kingdom (i.e., Great Britain and Northern Ireland), while the EMA is no longer involved in approving medicines intended for sale in Northern Ireland. In addition, an international recognition procedure has been in place since January 1, 2024, whereby the MHRA will have regard to decisions on the approval of marketing authorizations made by the EMA and certain other regulatory bodies when determining an application for a new United Kingdom marketing authorization.

Coverage, Pricing and Reimbursement

Sales of our products for which we receive approval will depend, in part, on the extent to which they will be covered by third-party payors, such as government health programs, commercial insurance and managed healthcare organizations. There may be significant delays in obtaining coverage and reimbursement for approved products, and coverage may be more limited than the purposes for which the product is approved by the FDA or regulatory authorities in other countries. It is time consuming and expensive to seek reimbursement from third-party payors. Moreover, eligibility for reimbursement does not imply that any product will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim payments for new products, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Payment rates may vary according to the use of the product and the clinical setting in which it is used, may be based on payments allowed for lower cost products that are already reimbursed and may be incorporated into existing payments for other services. Net prices for products may be reduced by mandatory discounts or rebates required by third-party payors and by any future relaxation of laws that presently restrict imports of products from countries where they may be sold at lower prices than in the United States.

In the United States, third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies, but they also have their own methods and approval process apart from Medicare coverage and reimbursement determinations. Accordingly, one third-party payor's determination to provide coverage for a product does not assure that other payors will also provide coverage for the product. The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. Third-party payors are increasingly challenging the prices charged, examining the medical necessity, and reviewing the cost-effectiveness of medical products and services and imposing controls to manage costs. Third-party payors may limit coverage to specific products on an approved list, also known as a formulary, which might not include all of the approved products for a particular indication.

A payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a product does not assure that other payors will also provide coverage and reimbursement for the product, and the level of coverage and reimbursement can differ significantly from payor to payor. Third-party reimbursement and coverage for our product candidates for which we receive approval may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development.

Additionally, the containment of healthcare costs has become a priority of federal and state governments and the prices of therapeutics have been a focus in this effort. The U.S. government, state legislatures and foreign governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic and biosimilar products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our net revenue and results. If third-party payors do not consider our

products to be cost-effective compared to other therapies, they may not cover our products after approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to sell our products on a profitable basis. In addition, companion diagnostic tests require coverage and reimbursement separate and apart from the coverage and reimbursement for their companion pharmaceutical or biological products. Similar challenges to obtaining coverage and reimbursement for the pharmaceutical or biological products apply to companion diagnostics.

Moreover, in some foreign countries, the proposed pricing for a product and therapeutic candidate must be approved before it may be lawfully marketed. The requirements governing therapeutic pricing 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. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our therapeutic candidates. Historically, therapeutic candidates launched in the EU do not follow price structures of the United States and generally tend to be significantly lower.

Healthcare Reform

In the United States and some foreign jurisdictions, there have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product and therapeutic candidates, restrict or regulate post-approval activities, and affect the ability to profitably sell product and therapeutic candidates that obtain marketing approval. The FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay marketing approval of our product and therapeutic candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we otherwise may have obtained and we may not achieve or sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations.

Moreover, among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. For example, the Affordable Care Act, or ACA, was enacted in March 2010 and has had a significant impact on the health care industry in the United States. It also included the BPCIA, which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. Among the provisions of the ACA of importance to our potential drug candidates are the implementation of a new methodology for calculating rebates owed by manufacturers under the Medicaid Drug Rebate Program for drugs that are inhaled, infused, instilled, implanted or injected; an increase of the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program; expanding manufacturer Medicaid rebate liability to include utilization under Medicaid managed care organizations; and establishing annual fees on manufacturers of certain branded prescription drugs.

Since its enactment, certain provisions of the ACA have been subject to judicial, executive, and legislative challenges. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Thus, the ACA will remain in effect in its current form.

As another example, the American Rescue Plan Act of 2021 included a provision that eliminated the statutory cap on manufacturer Medicaid rebates. Beginning in January 2024, Medicaid rebates are no longer capped at 100 percent of the drug's average manufacturer price.

Moreover, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship

between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products.

Most significantly, in August 2022, the Inflation Reduction Act of 2022, or IRA, was signed into law. This statute marks the most significant action by Congress with respect to the pharmaceutical industry since adoption of the ACA in 2010. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare, with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023); redesigns the Medicare Part D benefit (beginning in 2024); and replaces the Part D coverage gap discount program with a new manufacturer discount program (beginning in 2025). CMS has published the negotiated prices for the initial ten drugs, which will first be effective in 2026, and has published the list of the subsequent 15 drugs that will be subject to negotiation. The IRA permits the Secretary of the 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, although the Medicare drug price negotiation program is currently subject to legal challenges. While the impact of the IRA on the pharmaceutical industry cannot yet be fully determined, it is likely to be significant.

Individual states in the United States have also increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure, drug price reporting and other transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Some states have enacted legislation creating so-called prescription drug affordability boards, which ultimately may attempt to impose price limits on certain drugs in these states.

We expect that further legislative changes or additions to the ACA, the IRA, the Medicare and Medicaid programs, and changes stemming from other healthcare reform measures, especially with regard to healthcare access, financing or other legislation in individual states, could have a material adverse effect on the health care industry in the United States.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. We expect that additional state and federal health care reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for health care products and services.

Other Healthcare Laws

Our current and future business operations are subject to healthcare regulation and enforcement by the federal government and the states and foreign governments where we research, and, if approved, market, sell and distribute our therapeutic candidates. These laws include, without limitation, state and federal anti-kickback, fraud and abuse, false claims, physician sunshine and drug pricing transparency laws and regulations such as:

- The federal Anti-Kickback Statute prohibits, among other things, any person from knowingly and willfully offering, soliciting, receiving or paying remuneration, directly or indirectly, to induce either the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs. The federal Anti-Kickback Statute is broadly interpreted and aggressively enforced with the result that beneficial commercial arrangements can be penalized in the healthcare industry. In the past, the government has enforced the federal Anti-Kickback Statute to reach large settlements with healthcare companies based on a variety of arrangements, including sham consulting and other financial arrangements with physicians. Penalties for violating the federal Anti-Kickback Statute include imprisonment, fines and possible exclusion from federal healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, 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 civil False Claims Act;

- The federal civil and criminal false claims laws, including the civil False Claims Act, and civil monetary penalty laws, prohibit, among other things, knowingly presenting or causing the presentation of a false, fictitious or fraudulent claim for payment to the U.S. government, knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to the U.S. government, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U.S. government. Actions under these laws may be brought by the Attorney General or as a qui tam action by a private individual in the name of the government. The federal government uses these laws, and the accompanying threat of significant liability, in its investigation and prosecution of pharmaceutical and biotechnology companies throughout the U.S., for example, in connection with the promotion of products for unapproved uses and other allegedly unlawful sales and marketing practices. If an entity is found to have violated the False Claims Act, it must pay three times the actual damages sustained by the government, plus mandatory and substantial civil penalties;
- The Health Insurance Portability and Accountability Act of 1996 and its accompanying regulations, or HIPAA, created new federal, civil and criminal statutes that prohibit among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- The Physician Payments Sunshine Act, enacted as part of the ACA, among other things, imposes reporting requirements on manufacturers of FDA-approved drugs, devices, biologics and medical supplies covered by Medicare or Medicaid to report, on an annual basis, to CMS information related to payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors), teaching hospitals and certain advanced non-physician healthcare practitioners, as well as ownership and investment interests held by physicians and their immediate family members. The law provides for the imposition of civil monetary penalties, and payments reported also have the potential to draw scrutiny on payments and relationships with physicians, which may have implications under the Anti-Kickback Statute and other healthcare laws; and
- Analogous state laws and regulations, such as state anti-kickback and false claims laws which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state laws which require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug and therapeutic biologics manufacturers to report information related to payments to physicians and other healthcare providers or marketing expenditures and pricing information; and state and local laws which require the registration of pharmaceutical sales representatives.

Ensuring that our current and future business arrangements with third parties comply with applicable healthcare laws and regulations could involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any such requirements, we may be subject to significant civil, criminal and administrative penalties, including monetary damages, fines, disgorgement, imprisonment, loss of eligibility to obtain approvals from the FDA, exclusion from participation in government contracting, healthcare reimbursement or other government programs, including Medicare and Medicaid, reputational harm, diminished profits and future earnings, additional reporting requirements if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with any of these laws, and the curtailment or restructuring of our operations.

U.S. and European Data Privacy and Security Laws

Numerous state, federal and foreign laws, regulations and standards govern the collection, use, access to, confidentiality and security of health-related and other personal information, and could apply now or in the future to our operations or the operations of our partners. In the United States, numerous federal and state laws and

regulations, including data breach notification laws, health information privacy and security laws and consumer protection laws and regulations govern the collection, use, disclosure, and protection of health-related and other personal information. In addition, certain foreign laws govern the privacy and security of personal data, including health-related data. For example, the European Union General Data Protection Regulation, or the EU GDPR, and the United Kingdom General Data Protection Regulation and Data Protection Act 2018, or collectively, the UK GDPR (the EU GDPR and UK GDPR together referred to as the "GDPR"), impose comprehensive data privacy compliance obligations in relation to the collection and use of data relating to an identifiable living individual or "personal data", including a principle of accountability and the obligation to demonstrate compliance through policies, procedures, training and audit, as well as regulating cross-border transfers of personal data out of the European Economic Area, or the EEA, and the UK. Privacy and security laws, regulations, and other obligations are constantly evolving, may conflict with each other to complicate compliance efforts, and can result in investigations, proceedings, or actions that lead to significant civil and/or criminal penalties and restrictions on data processing.

Other Laws and Regulations

Our present business is, and our future business may be, subject to regulation under the Clean Air Act, the Clean Water Act, the Comprehensive Environmental Response, Compensation and Liability Act, the National Environmental Policy Act, the Toxic Substances Control Act, the Resource Conservation and Recovery Act, national restrictions, and other current and potential future local, state, federal, and foreign regulations. See "Risk Factors — Risks Related to Government Regulation — If we do not comply with laws regulating the protection of the environment and health and human safety, our business could be adversely affected."

Manufacturing

We do not own or operate manufacturing facilities for the production of any of our therapeutic candidates, nor do we have plans to develop our own manufacturing operations in the foreseeable future. We presently have relationships with suppliers for the manufacture of supplies for all of our required raw materials, antibodies, and other biologics for our preclinical research, clinical trials, and if and when applicable, commercialization. We currently employ internal resources to manage our manufacturing relationships.

Human Capital Resources

Our employees are a key factor in our ability to achieve our mission to discover and develop effective biologic therapeutics for people with life-threatening conditions. We believe that our future success depends on our continued ability to identify, recruit, retain, and incentivize our management team and our clinical, scientific, and other employees. Our ability to do so depends on factors including our Company culture, compensation and benefits, growth and development opportunities, and prioritization of employee safety.

Employee Profile

As of December 31, 2024, we had 161 employees, 156 of whom were full-time, 129 of whom were engaged in research and development activity, and 73 of which hold advanced degrees, including but not limited to Ph.D., M.D., PharmD, J.D., MBA, and other master's degrees. None of the employees are represented by a labor union and we believe we maintain good relations with our employees. Our employees represent a broad range of backgrounds and bring a wide array of perspectives and experiences. We believe this allows us to better drive innovation and achieve our mission.

Employee Conduct & Ethics

We adopted corporate policies, including a Code of Conduct and Ethics and Whistleblower Policy, which apply to all of our employees. All employees complete a mandatory public company training session and are required to abide by, review and confirm compliance to the Company's Corporate Code of Conduct and Ethics and Whistleblower Policy, as well as our Insider Trading Policy governing trading by Company personnel in the Company's securities. We have established a whistleblower reporting hotline to enable our employees to anonymously report any suspected violations of these policies. In addition, the Company requires employees to complete Anti-Harassment Training, with employees who work in a management capacity required to complete additional trainings in Harassment Prevention.

Employee Compensation and Benefits

Our compensation programs are designed to reward and support our employees in order to continue to attract and retain top talent. Our compensation includes:

- Employee base salaries that are competitive and consistent with employee positions, skill levels, experience, and knowledge;
- Stock-based compensation awards which help to align the interests of our stockholders with those of our employees;
- Bonus award plans for all full-time employees;
- Retirement savings options and matching contributions;
- Fully covered healthcare benefits for all full-time employees and their dependents;
- Unlimited vacation benefit for all full-time employees; and
- Parental leave and other leave options available to all employees.

Employee Growth and Development

We are committed to fostering and growing talent within the biopharmaceutical and life sciences space. We provide internship opportunities for students interested in biotechnology and science within our research and development departments. Many of our interns have continued on to join the Company in a full-time position after graduation. Our hiring process is transparent and we are an equal opportunity employer and prohibits all forms of unlawful discrimination in accordance with applicable law. Many of our employees hold advanced degrees, as well as professional licenses and certifications; however, the Company equally commits resources to advancing all of our employees with a range of educational backgrounds. We offer tuition reimbursement aimed at growth and career development, as well as the opportunity for employees to attend relevant conferences and symposiums. In addition, we offer in-house coaching opportunities to refine or develop professional skills as our employees become managers and plan their career growth.

Employee Wellness, Health, and Safety

We are strongly committed to the health and safety of our employees and strive to maintain the highest possible level of safety in our workplace. We require annual workplace safety training to reinforce workplace safety procedures that may be useful in the event of emergency situations and to assist our employees in helping to prevent workplace accidents. Our Environmental Health and Safety Committee, which is comprised of numerous cross-departmental members, meets regularly to review workplace safety and adherence to safety policies.

Corporate Information

The Company was incorporated as Ibex SpinCo, Inc. on January 8, 2024 under the laws of the State of Delaware as a direct, wholly-owned subsidiary of the Former Parent. We changed our name from Ibex SpinCo, Inc. to Inhibrx Biosciences, Inc. on January 25, 2024. Our corporate headquarters are located at 11025 N. Torrey Pines Road, Suite 140, La Jolla, CA 92037, and our telephone number is (858) 795-4220. Our website address is www.inhibrx.com. Information contained on, or that can be accessed through, our website is not part of, and is not incorporated into, this Annual Report.

Available Information

Our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and all amendments to those reports are and will be available to you free of charge through the "Investors" section on our website as soon as reasonably practicable after such materials have been electronically filed with, or furnished to, the SEC. The SEC maintains an internet site (http://www.sec.gov) that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC.

Properties

Our headquarters are located in La Jolla, California where we currently lease approximately 43,000 square feet of laboratory and office space under a lease that expires in 2028. We have an option to extend the lease an additional three years. We believe that this space is sufficient to meet our needs for the foreseeable future and that any additional space we may require will be available on commercially reasonable terms.

Legal Proceedings

Except as disclosed below, we are not currently a party to any material legal proceedings. From time to time, we may become involved in legal proceedings arising in the ordinary course of our business. Regardless of outcome, litigation can have an adverse impact on us due to defense and settlement costs, diversion of management resources, negative publicity, reputational harm and other factors.

In November 2024, the Company was successful in the trade secrets case brought against it by I-Mab Biopharma in the United States District Court for the District of Delaware, with the jury rejecting all allegations of misappropriation before it. In January 2025, the parties reached a settlement as to all asserted claims of misappropriation, including those claims not tried to the jury. Pursuant to that agreement, the Court dismissed the action with prejudice.

Emerging Growth Company and Smaller Reporting Company Status

We qualify as an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012, or JOBS Act, and we are eligible to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies." These exemptions generally include, but are not limited to, not being required to comply with the auditor attestation requirements of Section 404, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We plan to take advantage of some or all of the reduced regulatory and reporting requirements that will be available to us as long as we qualify as an emerging growth company, except that we have irrevocably elected not to take advantage of the extension of time to comply with new or revised financial accounting standards available under Section 102(b) of the JOBS Act.

We will, in general, remain as an emerging growth company for up to five full fiscal years following the completion of the Distribution. We would cease to be an emerging growth company and, therefore, become ineligible to rely on the above exemptions, if we:

- have more than $1.235 billion in annual revenue in a fiscal year;
- issue more than $1 billion of non-convertible debt during the preceding three-year period; or
- become a "large accelerated filer" as defined in Exchange Act Rule 12b-2, which would occur after: (i) we have filed at least one annual report pursuant to the Exchange Act; (ii) we have been an SEC-reporting company for at least twelve months; and (iii) the market value of our shares of common stock that is held by non-affiliates exceeds $700 million as of the last business day of our most recently completed second fiscal quarter.

We are also a "smaller reporting company," as defined by applicable rules of the SEC. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as our voting and non-voting common stock held by non-affiliates is less than $250.0 million measured on the last business day of our second fiscal quarter, or our annual revenue is less than $100.0 million during the most recently completed fiscal year and our voting and non-voting common stock held by non-affiliates is less than $700.0 million measured on the last business day of our second fiscal quarter.

Item 1A. Risk Factors.

Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below, together with all of the other information in this Annual Report, including our consolidated financial statements and related notes, before investing in our common stock. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties that we are unaware of, or that we currently believe are not material, may also become important factors that affect us. If any of the following risks occur, our business, operating results, financial condition, and prospects could be materially harmed. In that event, the price of our common stock could decline, and you could lose part or all of your investment.

Summary Risk Factors

Our business is subject to a number of risks of which you should be aware before making an investment decision. These risks are discussed more fully in the section of this Annual Report titled "Risk Factors". These risks include, among others, the following:

Risks Related to Our Financial Condition and Need for Additional Capital

- We have a limited operating history, have incurred significant operating losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future. We may never generate product revenue or become profitable in the future, or if we achieve profitability in the future, we may not be able to sustain it.
- Biotechnology product development is a highly speculative undertaking and involves a substantial degree of uncertainty. We have never generated any revenue from product sales and may never be profitable.
- We expect we will need to raise substantial additional funds to advance development of our therapeutic candidates, and we cannot guarantee this additional funding will be available on acceptable terms or at all. Failure to obtain this funding when needed may force us to delay, limit or terminate our development efforts and, if any of our therapeutic candidates are approved, our commercialization efforts.
- We may be adversely affected by the effects of inflation.

Risks Related to the Development, Clinical Testing and Commercialization of Our Therapeutic Candidates

- Our therapeutic candidates are in various stages of development and may fail or suffer delays (such as our partial clinical hold experienced in 2023 for ozekibart (INBRX-109)) that materially and adversely affect their commercial viability. If we are unable to advance our therapeutic candidates through clinical development, obtain marketing approval and ultimately commercialize our therapeutic candidates, or experience significant delays in doing so, our business will be materially harmed.
- We rely on third parties to conduct a portion of our clinical trials and certain of our preclinical studies and contract manufacturing. If these third parties do not perform as contractually required, fail to satisfy regulatory or legal requirements or miss expected deadlines, our development programs could be delayed with material and adverse effects on our business, financial condition, results of operations and prospects.

Risks Related to Our Organization and Operations

- We face significant competition and if our competitors develop and market products that are more effective, safer or less expensive than the therapeutic candidates we develop, our commercial opportunities will be negatively impacted.
- Our current operations are concentrated in one location, and we or the third parties upon whom we depend may be adversely affected by earthquakes, medical epidemics or pandemics, or other natural disasters.

Risks Related to Intellectual Property

- If we are not able to obtain and enforce patent protection for our technologies or therapeutic candidates, development and commercialization of our therapeutic candidates may be adversely affected.

Risks Related to Government Regulation

- We may be unable to obtain marketing approval for any product that we may develop and the marketing approval processes of the FDA and other comparable regulatory authorities outside the United States are lengthy, time-consuming and inherently unpredictable.

Risks Related to Ownership of Our Common Stock

- We do not know whether an active, liquid and orderly trading market will continue to develop or be sustained for our common stock and as a result it may be difficult for you to sell your shares of our common stock.
- We expect that our stock price may fluctuate significantly.
- Our executive officers, directors and holders of more than 5% of our capital stock own a significant percentage of our stock and are able to exercise significant control over matters subject to stockholder approval.
- Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our technologies or therapeutic candidates.

Risks Related to Our Financial Condition and Need for Additional Capital

We have a limited operating history, have incurred significant operating losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future. We may never generate product revenue or become profitable in the future, or if we achieve profitability in the future, we may not be able to sustain it.

We are a clinical-stage biopharmaceutical company. To date, we have financed our operations through equity and debt financings, license and milestone revenue and grants. We have incurred significant recurring operating losses since our inception. We expect to incur additional losses in future years as we execute our plan to continue our discovery, research and development activities, including the manufacturing of and ongoing and planned preclinical and clinical development and commercialization of our therapeutic candidates. We are unable to predict the extent of any future losses or when we will become profitable in the future, if ever. 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, maintain our research and development efforts, expand our business or continue our operations. A decline in the value of our Company could also cause you to lose all or part of your investment.

Biotechnology product development is a highly speculative undertaking and involves a substantial degree of uncertainty. We have never generated any revenue from product sales and may never be profitable.

We have devoted substantially all of our financial resources and efforts to developing our therapeutic candidates, identifying potential therapeutic candidates and conducting preclinical studies and clinical trials. We are still in the development stage for all of our therapeutic candidates, and while we have demonstrated an ability to successfully conduct and complete certain of our clinical trials, we have yet to demonstrate an ability to conduct pivotal clinical trials, obtain marketing approval, 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. Consequently, we have no meaningful operations upon which to evaluate our business and predictions about our future success or viability may not be as accurate as they could be if we had more experience developing therapeutic candidates. Our ability to generate revenue and achieve profitability depends in large part on our ability, alone or with license partners, to achieve milestones and to successfully complete the development of, obtain the necessary marketing approvals for, and commercialize, our therapeutic candidates. Even if we achieve development or commercial milestones, generate product royalties or generate product sales, we may never achieve or sustain profitability on a quarterly or annual basis. We do not anticipate generating revenue from sales of products for the foreseeable future. Our ability to generate future revenue from product sales depends heavily on our success in:

- completing clinical trials through all phases of clinical development of our current therapeutic candidates, including ozekibart (INBRX-109) and INBRX-106;
- advancing preclinical therapeutic candidates into clinical development;
- seeking and obtaining marketing approvals for our therapeutic candidates that successfully complete clinical trials;
- obtaining satisfactory acceptance, formulary placement coverage and adequate reimbursement for our approved products from third-party payors, including private health insurers, managed care providers and governmental payor programs, including Medicare and Medicaid;

- launching and commercializing products for which we obtain marketing approval successfully establishing a sales force, marketing and distribution infrastructure;
- establishing and maintaining supply and manufacturing relationships with third parties;
- obtaining market acceptance of any approved products by physicians, patients, third-party payors and the medical community;
- maintaining, protecting, expanding and enforcing our intellectual property portfolio;
- implementing additional internal systems and infrastructure, as needed; and
- attracting, hiring and retaining qualified personnel.

Because of the numerous risks and uncertainties associated with biological product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. If we are required by the FDA or other comparable foreign authorities to perform preclinical studies or clinical trials in addition to those we currently anticipate, or if there are any delays in completing our clinical trials or the development of any of our therapeutic candidates, our expenses could increase and revenue could be further delayed.

We expect we will need to raise substantial additional funds to advance development of our therapeutic candidates, and we cannot guarantee this additional funding will be available on acceptable terms or at all. Failure to obtain this funding when needed may force us to delay, limit or terminate our development efforts and, if any of our therapeutic candidates are approved, our commercialization efforts.

As of December 31, 2024, we had $152.6 million in cash and cash equivalents. We expect our expenses to increase in future years as we execute our plan to continue our discovery, research and development activities, including the ongoing and planned preclinical and clinical development and commercialization of our therapeutic candidates. Identifying potential therapeutic candidates and conducting preclinical testing and clinical trials are time consuming, expensive and uncertain processes that take years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, our therapeutic candidates, if approved, may not achieve commercial success.

We believe that our existing cash and cash equivalents will be sufficient to fund our planned operations through at least the 12-month period following the date of this Annual Report. However, changing circumstances or inaccurate estimates by us may cause us to use capital significantly faster than we currently anticipate, and we may need to spend more money than currently expected because of circumstances beyond our control. For example, our current and planned preclinical studies and clinical trials for our current therapeutic candidates or other therapeutic candidates we may seek to develop may encounter technical, enrollment or other issues that could cause our development costs to increase more than we expect, or we could expand our clinical trials to additional indications which could increase clinical trial expenses. Because successful development of our therapeutic candidates is uncertain, we are unable to estimate the actual funds we will require to complete research and development and commercialize our therapeutic candidates. Our ability to raise additional funds will depend on financial, economic and market conditions and other factors, over which we may have no or limited control. In addition, our ability to obtain future funding when needed through equity financings, debt financings or strategic collaborations may be challenging in light of recent market and macroeconomic conditions, which have been particularly challenging for research and development life science companies.

If adequate funds are not available on commercially acceptable terms when needed, we may be forced to delay, reduce or terminate the development or commercialization of all or part of our research programs or clinical therapeutic candidates, or we may be unable to take advantage of future business opportunities. In addition, any additional capital raising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our current and future therapeutic candidates.

Raising additional capital by issuing equity or debt securities may cause dilution to existing stockholders, and raising funds through lending and licensing or collaboration agreements may restrict our operations or require us to relinquish proprietary rights.

Until such time as we can generate substantial revenue from product sales, if ever, we expect to finance our cash needs through a combination of equity and debt financings, strategic collaborations and license and development agreements. We do not have any committed external source of funds. To the extent that we raise additional capital

by issuing equity securities, our existing stockholders' ownership may experience substantial dilution, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a stockholder. Equity and debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as redeeming our shares, making investments, incurring additional debt, making capital expenditures or declaring dividends. The incurrence of indebtedness could result in increased fixed payment obligations and we may be required to agree to certain restrictive covenants therein, 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 affect our ability to conduct our business. For example, we entered into a loan and security agreement with Oxford Finance LLC and other lenders, or collectively, Oxford, which contains certain restrictive covenants as discussed below in "Risk Factors – We have a significant amount of debt which may affect our ability to operate our business and secure additional financing in the future. If we fail to comply with the terms of our loan agreement with Oxford, our business, prospects and results of operations could be materially and adversely affected."

If we raise additional capital through collaborations, strategic alliances or third-party licensing agreements, we may have to relinquish valuable rights to our intellectual property, future revenue streams, research programs or therapeutics candidates, or grant licenses on terms that may not be favorable to us. If we are unable to raise additional capital through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts, or grant rights to develop and market therapeutic candidates that we would otherwise develop and market ourselves.

We may be adversely affected by the effects of inflation.

Inflation has the potential to adversely affect our liquidity, business, financial condition and results of operations by increasing our overall cost structure. The existence of inflation in the economy has resulted in, and may continue to result in, higher interest rates and capital costs, shipping costs, supply shortages, increased costs of labor, weakening exchange rates and other similar effects. Recently, inflation has increased throughout the U.S. economy. Inflation can adversely affect us by increasing the costs of clinical trials and research, the development of our therapeutic candidates, administration and other costs of doing business. We may experience increases in the prices of labor and other costs of doing business. In an inflationary environment, cost increases may outpace our expectations, causing us to use our cash and other liquid assets faster than forecasted. If this happens, we may need to raise additional capital to fund our operations, which may not be available in sufficient amounts or on reasonable terms, if at all, sooner than expected.

We maintain our cash and cash equivalents at financial institutions. The failure of financial institutions could adversely affect our ability to pay our operational expenses or make other payments.

Previous and potential future disruptions in access to bank deposits or lending commitments due to bank failure have contributed to increased volatility and could materially and adversely affect our liquidity, our business and financial condition. The closures of financial institutions and their placement into receivership with the Federal Deposit Insurance Corporation, or FDIC, created bank-specific and broader financial institution liquidity risk and concerns. Future adverse developments with respect to specific financial institutions or the broader financial services industry may lead to market-wide liquidity shortages. The failure of any bank in which we deposit our funds could reduce the amount of cash we have available for our operations or delay our ability to access such funds. Any such failure may increase the possibility of a sustained deterioration of financial market liquidity, or illiquidity at clearing, cash management and/or custodial financial institutions. In the event we have a commercial relationship with a bank that has failed or is otherwise distressed, we may experience delays or other issues in meeting our financial obligations. If other banks and financial institutions enter receivership or become insolvent in the future in response to financial conditions affecting the banking system and financial markets, our ability to access our cash and cash equivalents and investments may be threatened and could have a material adverse effect on our business and financial condition.

Risks Related to the Development, Clinical Testing and Commercialization of Our Therapeutic Candidates

Our therapeutic candidates are in various stages of development and may fail or suffer delays that materially and adversely affect their commercial viability. If we are unable to advance our therapeutic candidates through clinical development, obtain marketing approval and ultimately commercialize our therapeutic candidates, or experience significant delays in doing so, our business will be materially harmed.

Clinical and preclinical development is expensive and can take many years to complete, and its outcome is inherently uncertain. We cannot guarantee that any clinical trials or preclinical studies will be conducted as planned, including whether we our able to meet expected timeframes for data readouts, or completed on schedule, if at all, and failure can occur at any time during the trial or study process. For instance, we independently decided to cease development of INBRX-105 as we determined, after evaluation of the totality of the data from the expansion cohorts, that the initial signal was not sufficiently validated to support the continuation of the program. Despite promising preclinical or clinical results, any therapeutic candidate can unexpectedly fail at any stage of clinical or preclinical development. The historical failure rate for therapeutic candidates in our industry is high, particularly in the earlier stages of development.

Our two therapeutic candidates are still currently in clinical trials (ozekibart (INBRX-109) and INBRX-106). We have no products on the market and our ability to achieve and sustain profitability depends on obtaining marketing approvals for and successfully commercializing our therapeutic candidates. Before obtaining marketing approval for the commercial distribution of our therapeutic candidates, we must conduct extensive preclinical tests and clinical trials to demonstrate sufficient safety, purity, and potency (or efficacy) of our therapeutic candidates in patients. Before we can initiate clinical trials for any therapeutic candidates, we must submit the results of preclinical studies to the FDA or comparable foreign regulatory authorities along with other information, including information about the candidate's chemistry, manufacturing and controls and our proposed clinical trial protocol, as part of an Investigational New Drug Application, or IND, or similar regulatory submission. The FDA or comparable foreign regulatory authorities may require us to conduct additional preclinical studies for any therapeutic candidate before it allows us to initiate clinical trials under any IND or similar regulatory submission, which may lead to delays and increase the costs of our development programs.

Moreover, failure can occur at any time during the clinical trial process and our future clinical trial results may not be successful. If we experience additional delays or fail to develop or again terminate development of a therapeutic candidate in our pipeline, we may not have the financial resources to continue development of, or to modify existing or to enter into new license or collaboration for, a therapeutic candidate. Other issues that may again delay or potentially prevent us from completing our ongoing and planned 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;
- obtaining allowance or approval from regulatory authorities to commence a trial or reaching a consensus with regulatory authorities on trial design;
- the FDA or comparable foreign regulatory authorities disagreeing as to the design or implementation of our clinical trials;
- any failure or delay in reaching an agreement with contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- delays in identifying, recruiting and training suitable clinical investigators;
- obtaining approval from one or more institutional review boards, or IRBs, or ethics committees at clinical trial sites;
- IRBs refusing to approve, suspending or terminating the trial at an investigational site, precluding enrollment of additional subjects, or withdrawing their approval of the trial;
- changes or amendments to the clinical trial protocol;
- clinical sites deviating from the trial protocol or dropping out of a trial;
- failure by our CROs to perform in accordance with Good Clinical Practice, or GCP, requirements or applicable regulatory rules and guidelines in other countries;
- manufacturing sufficient quantities of our therapeutic candidates, or in obtaining sufficient quantities of combination therapies for use in clinical trials;

- subjects failing to enroll or remain in our trials at the rate we expect, or failing to return for post-treatment follow-up, including subjects failing to remain in our trials;
- patients choosing an alternative product for the indications for which we are developing our therapeutic candidates, or participating in competing clinical trials;
- lack of adequate funding to continue a clinical trial, or costs being greater than we anticipate;
- subjects experiencing severe or serious unexpected drug-related adverse effects;
- occurrence of serious adverse events in trials of the same class of agents conducted by other companies that could be considered similar to our therapeutic candidates;
- selection of clinical endpoints that require prolonged periods of clinical observation or extended analysis of the resulting data;
- delays or failure by our contract manufacturers or us to make any necessary changes to such manufacturing process, or failure of our contract manufacturers to produce clinical trial materials in accordance with current Good Manufacturing Practice, or cGMP, regulations or other applicable requirements; and
- third parties being unwilling or unable to satisfy their contractual obligations to us in a timely manner.

The therapeutic candidates we pursue may not demonstrate the necessary safety or efficacy requirements for marketing approval.

A clinical trial may be suspended, partially suspended or terminated by us, the IRBs overseeing such trials, the Data Safety Monitoring Board for such trial or by the FDA or other regulatory authorities 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 or other regulatory authorities resulting in the imposition of a clinical hold or partial clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug or therapeutic biologic, changes in governmental regulations, administrative actions or lack of adequate funding to continue the clinical trial. Clinical holds may be placed prior to a clinical trial even beginning, in order to address potential safety and risk concerns of regulatory authorities, and partial or complete clinical holds can be imposed at any time during a trial. For example, in early 2023, the Phase 2 trial of ozekibart (INBRX-109) was placed on partial clinical hold by the FDA, and the Former Parent paused patient enrollment in the trial, following the occurrence of a fatal serious adverse event (grade 5) of hepatotoxicity (or hepatic failure) triggering the predefined stopping rules built into the protocol. The FDA lifted the hold in April 2023 after the Former Parent amended the trial protocol to include additional screening criteria and to make other changes to address patients who may be at risk of significant hepatotoxicity. Furthermore, while we perform certain similar functions internally, we expect to rely on contract research organizations, or CROs, and clinical trial sites to ensure proper and timely conduct of our clinical trials and while we expect to enter into and have entered into agreements governing those CROs' committed activities, we have limited influence over their actual performance.

If we experience delays in the completion of, or termination of, any clinical trial of our therapeutic candidates, the commercial prospects of our therapeutic candidates may be harmed, and our ability to generate product revenue or receive royalties from any of these therapeutic candidates may be delayed. Any delays in completing our clinical trials may increase our costs, slow down our product development and approval process and jeopardize our ability to commence product sales and generate revenue. If we were to cancel the development of any of our therapeutic candidates, we may still be required to pay certain non-cancellable commitments to our CROs under the terms of our various CRO contracts. Any of these occurrences may materially and adversely affect our business, financial condition, results of operations and prospects. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of marketing approval of our therapeutic candidates.

Our approach to the discovery and development of therapeutic candidates is based on our proprietary modular protein engineering platforms and is novel and unproven, and the cost and time to develop them and the likelihood of success may be more uncertain than if we had employed more established drug development approaches.

The success of our business depends in part upon our ability to identify, develop and commercialize therapeutics and therapeutic candidates (including ozekibart (INBRX-109) and INBRX-106) based on our proprietary modular

protein engineering platforms, which leverage a novel and unproven therapeutic approach. Our research methodology and novel approach to oncology and rare disease using our proprietary modular protein engineering platforms may be unsuccessful in identifying additional therapeutic candidates, and any therapeutic candidates based on our technology may be shown to have harmful side effects or may have other characteristics that may necessitate additional clinical testing that would extend development timelines and be more costly, or make the therapeutic candidates unmarketable or unlikely to receive marketing approval. If any of our therapeutic candidates prove to be ineffective, unsafe or commercially unviable, our entire pipeline could have little, if any, value, and it may prove to be difficult or impossible to finance or further continue development of our pipeline. We have observed serious adverse events in our Phase 1/2 clinical trial of INBRX-106, as well as our Phase 1 and Phase 2 clinical trials of ozekibart (INBRX-109) for chondrosarcoma, for which we have been subject to a prior partial clinical hold.

As noted in the risk factor "We face significant competition and if our competitors develop and market products that are more effective, safer or less expensive than the therapeutic candidates we develop, our commercial opportunities will be negatively impacted," the life science industry is highly competitive, and development of products, even therapeutic candidates with novel and unproven technology such as our therapeutic candidates, is highly competitive. If we fail to stay at the forefront of technological change in utilizing our protein engineering platforms to create and develop therapeutic candidates, we may be unable to compete effectively. Our competitors may render our protein engineering platforms obsolete or may limit the commercial value of our therapeutic candidates, by advances in existing technological approaches or the development of new or different approaches, potentially eliminating the advantages in our drug discovery process that we believe we derive from our research approach and proprietary technologies. By contrast, adverse developments with respect to other companies that attempt to use a similar approach to our approach may adversely impact the actual or perceived value of our proprietary modular protein engineering platforms and potential of our proprietary modular protein engineering platforms-based therapeutic candidates.

Moreover, advancing our therapeutic candidates as novel candidates creates other significant challenges for us, including educating medical personnel regarding a novel class of modular protein therapeutics, as well as the challenges of incorporating our therapeutic candidates, if ever approved, into treatment regimens.

If any of these challenges, events or circumstances occur, we may be forced to abandon our development efforts for a program or programs, which would harm our business, financial condition, results of operation and prospects.

The results of preclinical studies and early stage clinical trials of our therapeutic candidates may not be predictive of the results of later stage clinical trials. Initial results or observations in our ongoing clinical trials may not be indicative of results obtained when these trials are completed or in later stage trials.

Success in preclinical studies and early clinical trials does not ensure that later and pivotal clinical trials will generate the same results, or otherwise provide adequate data to demonstrate the safety and efficacy of a therapeutic candidate. Frequently, therapeutic candidates that have shown promising results in preclinical studies or early clinical trials have subsequently suffered significant setbacks in later or pivotal clinical trials. Our therapeutic candidates in clinical trials, including ozekibart (INBRX-109) and INBRX-106, may ultimately fail to show the desired safety and efficacy in clinical trials despite having progressed through preclinical studies and despite any initial observations of single agent activity, stable disease or partial responses. There can be no assurance that any of our clinical trials will ultimately be successful or support further clinical development, including development in trials, of any of our therapeutic candidates. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in clinical development even after achieving promising results in earlier studies or trials, and any of these setbacks in our clinical development could have a material adverse effect on our business and operating results.

Our therapeutic candidates may cause undesirable side effects that could delay or prevent their marketing approval, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any.

Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. Undesirable side effects caused by our therapeutic candidates, whether used alone on in combination with other therapies, have in the past caused, could cause us or regulatory authorities to interrupt, delay

or halt clinical trials or the delay or denial of marketing approval by regulatory authorities, or, if such therapeutic candidates are approved, result in a more restrictive label and other post-approval requirements.

If our therapeutic candidates are associated with undesirable side effects or have unexpected characteristics in preclinical studies or clinical trials, when used alone or in combination with other approved products or investigational drugs, we may also need to interrupt, delay or abandon their development or limit development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective.

Results of our clinical trials could reveal a high and unacceptable severity of adverse side effects and it is possible that patients enrolled in these clinical trials could respond in unexpected ways. For instance, ozekibart (INBRX-109) and INBRX-106 are therapeutic candidates targeting oncology indications that are clinically evaluated in very sick populations. Certain trial participants, including participants evaluated in our trials for ozekibart (INBRX-109), have in the past and others may in the future experience side effects or serious adverse events that could be related to one of our therapeutic candidates. We have observed serious treatment related serious adverse events in our Phase 1/2 clinical trial of INBRX-106 which consisted of general disorders and administration site conditions, metabolism and nutrition disorders, gastrointestinal disorders, blood and lymphatic system disorders, cardiac disorders, cytokine release syndrome, infusion-related reactions, primary adrenal insufficiency, increased blood bilirubin, myositis, toxic encephalopathy, and acute kidney injury, and in our Phase 1 and Phase 2 clinical trials of ozekibart (INBRX-109) in chondrosarcoma which consisted of abnormal laboratory findings, gastrointestinal disorders, blood and lymphatic disorders, hepatobiliary disorders, general disorders and administration site conditions, infections, metabolism and nutrition disorders, tachycardia, posterior reversible encephalopathy syndrome, muscular weakness and renal and urinary disorders.

It may be difficult to establish safety in relatively small patient populations with rare diseases. Further, we intend to develop certain of our therapeutic candidates in combination with one or more cancer therapies. This combination may have additional side effects that were not present in preclinical studies or clinical trials of our therapeutic candidates conducted as a monotherapy or in combination with other cancer therapies. The uncertainty resulting from the use of our therapeutic candidates in combination with other cancer therapies may make it difficult to accurately predict side effects in future clinical trials.

These side effects could also affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Further, clinical trials by their nature utilize a sample of the potential patient population. Rare and severe side effects of our therapeutic candidates may only be uncovered with a significantly larger number of patients exposed to our therapeutic candidates.

In the event that any of our therapeutic candidates receives marketing approval and we or others identify undesirable side effects caused by our product (or potentially other therapeutics with similar mechanisms of action), any of the following adverse events could occur:

- we may be required to suspend marketing of a product, or we may decide to remove such product from the marketplace
- regulatory authorities may withdraw or modify their approval of the product;
- additional restrictions may be imposed on the marketing of the particular product or the manufacturing processes for the product or any component of the product;
- regulatory authorities may require the addition of safety-related labeling statements, such as a “black box” warning or a contraindication;
- we may be required to create a Medication Guide outlining the risks of such side effects for distribution to patients or to implement other aspects of a risk evaluation and mitigation strategy, or REMS, such as a restricted distribution program or educational programs for prescribers;
- we could be subject to fines, injunctions, or the imposition of criminal or civil penalties, or could be sued and held liable for harm caused to patients;
- the product may become less competitive; and
- our reputation may suffer.

In addition, adverse side effects caused by any therapeutics that may be similar in nature to our therapeutic candidates could delay or prevent marketing approval of our therapeutic candidates, limit the commercial profile of an approved label for our therapeutic candidates, or result in significant negative consequences for our therapeutic candidates following marketing approval, if any.

Any of the above described events could prevent us from achieving or maintaining market acceptance of our therapeutic candidates, if approved, and could delay, impede and/or substantially increase the costs of commercializing our therapeutic candidates thus significantly impacting our ability to successfully commercialize our therapeutic candidates and generate revenue. Any of the above described occurrences may materially and adversely affect our business, financial condition, results of operations and prospects.

We expect to develop certain of our therapeutic candidates in combination with other therapies, and safety or supply issues with combination use products may delay or prevent development and approval of our therapeutic candidates.

We intend to develop certain of our therapeutic candidates in combination with one or more approved or investigational cancer therapies. Even if any therapeutic candidate we develop were to receive marketing approval or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risks that the FDA or similar regulatory authorities outside of the United States could revoke approval of the therapy used in combination with our product or that safety, efficacy, manufacturing or supply issues could arise with any of those existing therapies. If the therapies we use in combination with our therapeutic candidates are replaced as the standard of care for the indications we choose for any of our therapeutic candidates, the FDA or similar regulatory authorities outside of the United States may require us to conduct additional clinical trials. The occurrence of any of these risks could result in our own products, if approved, being removed from the market or being less successful commercially. Developing combination therapies using approved therapeutics also exposes us to additional clinical risks, such as the requirement that we demonstrate the safety, purity, potency or efficacy of each active component of any combination regimen we may develop.

We also may evaluate our therapeutic candidates in combination with one or more cancer therapies that have not yet been approved for marketing by the FDA or similar regulatory authorities outside of the United States. We will not be able to market and sell any therapeutic candidate we develop in combination with an unapproved cancer therapy if that unapproved cancer therapy does not ultimately obtain marketing approval. In addition, unapproved cancer therapies face the same risks described with respect to our therapeutic candidates currently in development and clinical trials, including the potential for serious adverse events, delay in their clinical trials and lack of FDA approval.

If the FDA or similar regulatory authorities outside of the United States do not approve these other drugs or revoke their approval of, or if safety, efficacy, manufacturing, or supply issues arise with, the drugs we choose to evaluate in combination our therapeutic candidates, we may be unable to obtain approval of or market any such therapeutic candidate.

If we experience delays or difficulties in the enrollment of patients in clinical trials, our receipt of necessary marketing approvals could be delayed or prevented.

We may not be able to initiate or continue clinical trials for our therapeutic candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside the United States. Should any competitors have ongoing clinical trials for therapeutic candidates treating the same indications as our therapeutic candidates, patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' therapeutic candidates. The conditions for which we currently plan to evaluate our therapeutic candidates include orphan or rare diseases with limited patient pools from which to draw for clinical trials. The eligibility criteria of our clinical trials, once established, may further limit the pool of available trial participants.

Patient enrollment is affected by other factors including:

- the size and nature of the patient population
- the severity of the disease under investigation;

- the patient eligibility criteria for the study in question;
- the perceived risks and benefits of the therapeutic candidate under study;
- the availability and efficacy of available therapies for the disease or condition under investigation;
- clinicians' and patients' perceptions as to the potential advantages of the therapeutic candidate under investigation;
- our payments for conducting clinical trials;
- the ability to monitor patients adequately during and after treatment;
- the patient referral practices of physicians; and
- the proximity and availability of clinical trial sites for prospective patients.

Additionally, other pharmaceutical companies targeting these same diseases are recruiting clinical trial patients from these patient populations, which may make it more difficult to fully enroll any clinical trials. We also rely on, and will continue to rely on, CROs and clinical trial sites to ensure proper and timely conduct of our clinical trials and preclinical studies. Though we have entered into agreements governing their services, we will have limited influence over their actual performance. Our inability to enroll a sufficient number of patients for any of our clinical trials could result in significant delays and could require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our therapeutic candidates and in delays to commercially launching our therapeutic candidates, if approved, which would materially harm our business.

If we are required by the FDA or comparable foreign regulatory authority to obtain approval of a companion diagnostic test in connection with approval of any of our therapeutic candidates, and we do not obtain, or face delays in obtaining, FDA or foreign marketing approval of such companion diagnostic, our ability to commercialize our therapeutic candidates and generate revenue will be materially impaired.

If the FDA believes that the safe and effective use of any of our therapeutic candidates depends on an in vitro diagnostic it may require approval or clearance of that diagnostic as a companion diagnostic at the same time that the FDA approves our therapeutic candidates, if at all. According to FDA guidance, if the FDA determines that a companion diagnostic device is essential to the safe and effective use of a novel therapeutic product or indication, the FDA generally will not approve the therapeutic product or indication if the companion diagnostic is not also approved or cleared for that indication. Depending on the data from our clinical trials, we may decide to collaborate with diagnostic companies during our clinical trial enrollment process to help identify patients with characteristics that we believe will be most likely to respond to our therapeutic candidates. If a companion diagnostic is not commercially available in this situation, we may be required to develop or obtain an alternative companion diagnostic, that would be subject to regulatory approval requirements. The process of obtaining or creating such diagnostics is time-consuming and costly.

Companion diagnostics are developed in conjunction with clinical programs for the associated product and are subject to regulation as medical devices by the FDA and comparable foreign regulatory authorities, and the FDA has generally required premarket approval of companion diagnostics for cancer therapies. The approval or clearance of a companion diagnostic as part of the therapeutic product's further labeling limits the use of the therapeutic product to only those patients who express the specific characteristic that the companion diagnostic was developed to detect.

If the FDA or a comparable foreign regulatory authority requires approval or clearance of a companion diagnostic for any of our therapeutic candidates, whether before, simultaneously with, or after the candidate obtains marketing approval, we and/or third-party collaborators may encounter difficulties in developing and obtaining approval or clearance for these companion diagnostics. Any delay or failure by us or third-party collaborators to develop or obtain regulatory approval or clearance of a companion diagnostic could delay or prevent approval or continued marketing of the relevant product. We or our third-party collaborators may also experience delays in developing a sustainable, reproducible and scalable manufacturing process for the companion diagnostic or in transferring that process to commercial partners or negotiating insurance reimbursement plans, all of which may prevent us from completing our clinical trials or commercializing our therapeutic candidates, if approved, on a timely or profitable basis, if at all.

If we do not achieve our projected development and commercialization goals in the timeframes we announce and expect, the commercialization of any of our therapeutic candidates may be delayed, and our business may be harmed.

We have provided, and will continue to provide, a number of timing estimates regarding the initiation of clinical trials and clinical development milestones, and the expected availability of data resulting from these trials for certain of our therapeutic candidates. We expect to continue to estimate the timing of these types of development milestones and our expected timing for the accomplishment of various other scientific, clinical, regulatory and other product development objectives. From time to time, we may publicly announce the expected timing of some of these events and we have had to adjust our previously announced timing for certain of our therapeutic candidates. The achievement of many of these milestones and events may be outside of our control. All of these timing estimations are based on a variety of assumptions we make, which may cause the actual timing of these events to differ from the timing we expect, including:

- our available capital resources and our ability to obtain additional funding as needed;
- the rate of progress, costs and results of our clinical trials and research and development activities;
- our ability to identify and enroll patients who meet clinical trial eligibility criteria;
- our receipt of clinical trial allowances or approvals by the FDA and other regulatory authorities and the timing of these allowances and approvals;
- our ability to access sufficient, reliable and affordable supplies of materials used in the manufacture of our therapeutic candidates;
- the efforts of our licensees with respect to the commercialization of our therapeutic candidates;
- the securing of, costs related to, and timing issues associated with, manufacturing our therapeutic candidates and, if any of our therapeutic candidates are approved, associated with sales and marketing activities and the commercial manufacture of our therapeutic candidates; and
- circumstances arising from or relating to pandemics, regional conflicts, sanctions, geopolitical events, natural disasters or extreme weather events, including potential effects on the global supply chain, our manufacturers and the availability of raw materials needed for the research and development of our therapeutic candidates.

If we fail to achieve announced milestones in the timeframes we expect, the future marketing approval and commercialization of any of our therapeutic candidates may be delayed, and our business, financial condition, results of operations, and prospects may be harmed and our stock price may decline.

Initial, interim, topline and preliminary data from our clinical trials that we may announce, observe or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we publish initial, interim, topline or preliminary data from our clinical trials. These initial, interim, topline and preliminary data from our clinical trials that we may publish from time to time or that we may observe on an ongoing basis in our open-label trials may change as more data become available and, accordingly, they are not necessarily predictive of final results. Preliminary and interim data are subject to the risk that one or more of the clinical outcomes may materially change as participant enrollment continues, more participant data become available and we issue our final clinical trial report. Initial, interim, topline and preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, initial, interim, topline and preliminary data should be viewed with caution until the final data are available. Material adverse changes in the final data compared to the interim data could significantly harm our business prospects.

The market opportunities for any current or future therapeutic candidate we develop, if and when approved, may be limited to those patients who are ineligible for established therapies or for whom prior therapies have failed, and may be small or smaller than we may expect.

Cancer therapies are sometimes characterized as first-, second-, or third-line. When cancer is detected early enough, first-line therapy, usually chemotherapy, hormone therapy, surgery, radiation therapy or a combination of these, is sometimes adequate to cure the cancer or prolong life without a cure. Second- and third-line therapies are administered to patients when prior therapy is not effective. We expect to initially seek approval of certain of our

therapeutic candidates as a therapy for patients who have received one or more prior treatments. Subsequently, for those products that prove to be sufficiently beneficial, if any, we would expect to seek approval potentially as a first-line therapy, but there is no guarantee that therapeutic candidates we develop, even if approved, would be approved for first-line therapy, and, prior to any such approvals, we may have to conduct additional clinical trials.

The number of patients who have the cancers we are targeting may turn out to be small or smaller than expected. Additionally, the potentially addressable patient population for our current programs or future therapeutic candidates may be limited, if and when approved. Even if we obtain significant market share for any therapeutic candidate, if and when approved, if the potential target populations are small or smaller than expected, we may never achieve profitability without obtaining marketing approval for additional indications, including to be used as first- or second- or third-line therapy.

We rely on third parties to conduct a portion of our clinical trials and certain of our preclinical studies and contract manufacturing. If these third parties do not perform as contractually required, fail to satisfy regulatory or legal requirements or miss expected deadlines, our development programs could be delayed with material and adverse effects on our business, financial condition, results of operations and prospects.

While we expect to continue our current clinical trials and expect to initiate clinical trials in the near term for other therapeutic candidates, we do not independently conduct clinical trials. As such, while we perform certain functions internally, we currently rely on third-party CROs, clinical data management organizations and consultants to help us design, conduct, supervise and monitor clinical trials of our therapeutic candidates. As a result, we have less control over the timing, quality and other aspects of our clinical trials than we would have had we conducted them on our own. There is a limited number of third party service providers that specialize or have the expertise required to achieve our business objectives. If any of our relationships with these third-party CROs or clinical investigators terminate, we may not be able to enter into arrangements with alternative CROs or investigators or to do so on commercially reasonable terms. Further, these investigators, CROs and consultants are not our employees and we have limited control over the amount of time and resources that they dedicate to our programs. These third parties may have contractual relationships with other entities, some of which may be our competitors, which may draw time and resources from our programs. The third parties with which we contract might not be diligent, careful or timely in conducting our preclinical studies or clinical trials. If we cannot contract with acceptable third parties on commercially reasonable terms, or at all, or if these third parties do not carry out their contractual duties, satisfy the legal and regulatory requirements for the conduct of preclinical studies or clinical trials or meet expected deadlines for any reason, our clinical development programs could be delayed and otherwise adversely affected.

In all events, we will be responsible for ensuring that each of our preclinical studies and clinical trials is conducted in accordance with the general investigational plan and protocols for the relevant study or trial. Our reliance on third parties we do not control will not relieve us of these responsibilities and requirements. In addition, we and our CROs are required to comply with GLP and GCP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities with the respect to the conduct of preclinical studies and clinical trials. Regulatory authorities enforce GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs or trial sites fail to comply with applicable GLP, GCP or other requirements, the data generated in our clinical trials may be deemed unreliable, and the FDA or comparable foreign regulatory authorities may require us to perform additional preclinical studies clinical trials before approving our marketing applications, if ever. Any adverse development or delay in our clinical trials could have a material and adverse effect on our business, financial condition, results of operations and prospects.

Moreover, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA or comparable foreign regulatory authorities. The FDA or comparable foreign regulatory authority may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the study. The FDA or comparable foreign regulatory authority may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA or comparable foreign regulatory authority, as the case may be, and may ultimately lead to the denial of marketing approval of one or more of our therapeutic candidates.

We do not track our research and development expenses on a program-by-program basis, which may impact our ability to efficiently allocate resources and could adversely affect our financial condition and results of operation.

In accordance with the applicable accounting and regulatory requirements, we track all research and development expenses in the aggregate and do not measure or track such expenses on a program-by-program basis. As a result, we evaluate the effectiveness of any particular research and development expense using qualitative metrics such as patient data and discussions with our employees overseeing the particular program. Our approach to research and development expenses may limit our ability to accurately assess the cost-effectiveness and progress of individual programs, which could impact our strategic decision-making process. For instance, if our qualitative observations are inaccurate or if the CRO fails to adequately oversee the research and development activities of any program, we may continue to allocate resources to a program that is not cost-effective or underperforming, or conversely, we may underfund a program that could potentially yield significant returns. This could result in inefficient use of our resources and potentially impact our financial condition and results of operations. Moreover, our approach to tracking research and development expenses could potentially impact our ability to attract investors who scrutinize the allocation of research and development expenses as a measure of a company's management efficiency and strategic focus. If any such risk were to materialize, it could potentially impact our financial condition, results of operations, and ability to attract investments.

We may expend our limited resources to pursue a particular therapeutic candidate and fail to capitalize on therapeutic candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we focus on specific therapeutic candidates, development programs and specific indications. As a result, we may forgo or delay pursuit of opportunities with other therapeutic candidates that could have had greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable potential commercial therapeutics or profitable market opportunities. Our spending on current and future research and development programs and therapeutic candidates for specific indications may not yield any commercially viable therapeutic candidates. If we do not accurately evaluate the commercial potential or target market for a particular therapeutic candidate, we may relinquish valuable rights to that therapeutic candidate through collaborations, licenses and other similar arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such therapeutic candidate.

We may in the future enter into collaborations with third parties to develop our therapeutic candidates. If these collaborations are not successful, our business could be harmed.

We may enter into collaborations with third parties in the future. Any collaborations that we are party to may pose several risks, including the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not perform their obligations as expected;
- the clinical trials conducted as part of these collaborations may not be successful;
- collaborators may not pursue development and commercialization of any therapeutic candidates that achieve marketing approval or may elect not to continue or renew development or commercialization programs based on clinical trial results;
- changes in the collaborators' strategic focus or available funding or external factors, such as an acquisition, that divert resources or create competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for clinical trials, stop a clinical trial or abandon a therapeutic candidate, repeat or conduct new clinical trials or require a new formulation of a therapeutic candidate for clinical testing;
- we may not have access to, or may be restricted from disclosing, certain information regarding therapeutic candidates being developed or commercialized under a collaboration and, consequently, may have limited ability to inform our stockholders about the status of such therapeutic candidates;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our therapeutic candidates 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;
- therapeutic candidates developed in collaboration with us may be viewed by our collaborators as competitive with their own therapeutic candidates or products, which may cause collaborators to cease to devote, or limit, resources to the commercialization of our therapeutic candidates;
- a collaborator with marketing and distribution rights to one or more of our therapeutic candidates that achieve marketing approval may not commit sufficient resources to the marketing and distribution of any such therapeutic candidate;
- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;
- disputes may arise with respect to the ownership of intellectual property developed pursuant to our collaborations;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; and
- collaborations may be terminated for the convenience of the collaborator and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable therapeutic candidates.

In addition, we may have disagreements with these collaborators, including disagreements over proprietary rights, collaborator performance, contract interpretation or the preferred course of development of any therapeutic candidates. Any disagreement we may have with our collaborators, may cause delays or termination of the research, development or commercialization of our therapeutic candidates pursuant to the applicable agreement, may lead to additional responsibilities for us with respect to our therapeutic candidates or may result in litigation or arbitration, any of which would be time-consuming and expensive and which would likely divert the attention of our management from our core research and development activities. These types of disputes could materially harm our financial condition and our business.

The manufacture of biotechnology products is complex, and manufacturers often encounter difficulties in production. If we or any of our third party manufacturers encounter such difficulties, or otherwise fail to comply with their contractual obligations, the development or commercialization of our therapeutic candidates could be delayed or stopped.

While we have found that our therapeutic candidates can be readily manufactured at high yields with established processes used to produce therapeutic proteins, the manufacture of biotechnology products is generally complex and requires significant expertise and capital investment. We and our contract manufacturers must comply with current Good Manufacturing Practices, or cGMP, and similar foreign regulations and guidelines for clinical trial product manufacture and for commercial product manufacture. Manufacturers of biotechnology products often encounter difficulties in production, particularly in scaling up, addressing product quality, product comparability, validating production processes and mitigating potential sources of contamination. These problems include difficulties with raw material procurement, production costs and yields, quality control, product quality, including stability of the product, quality assurance testing, operator error, shortages of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. Furthermore, if microbial, viral or other contaminations are discovered in our therapeutics or in the manufacturing facilities in which our therapeutics are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination.

We cannot assure you that manufacturing problems, including supply chain disruptions of any of our therapeutic candidates or products will not occur in the future. Any delay or interruption in the supply of preclinical or clinical trial supplies or supply chain disruptions could delay the completion of these trials, increase the costs associated with maintaining these trial programs and, depending upon the period of delay, require us to commence new trials at additional expense or terminate trials completely.

If we were to experience an unexpected loss of supply of, or if any supplier were unable to meet our demand for any of our therapeutic candidates or future approved products we seek to commercialize, if any, we could experience

delays in our research or planned clinical studies or be forced to stop our development or commercialization efforts. We could be unable to find alternative suppliers of acceptable quality, in the appropriate volumes and at an acceptable cost. Moreover, our suppliers are often subject to strict manufacturing requirements and rigorous testing requirements, which could limit or delay production. The long transition periods needed to switch manufacturers and suppliers, if necessary, would significantly delay our clinical studies and the commercialization of our therapeutics, if approved, which would materially adversely affect our business, prospects, financial condition and results of operation.

We rely on third parties to supply and manufacture our therapeutic candidates, and we expect to continue to rely on third parties to manufacture and supply our therapeutics, if approved. The development of therapeutic candidates and the commercialization of any therapeutic candidates, if approved, could be stopped, delayed or made less profitable if any of these third parties fail to provide us with sufficient quantities of therapeutic candidates or therapeutics, fail to do so at acceptable quality levels or prices, or fail to maintain or achieve satisfactory regulatory compliance.

We do not currently have, nor do we plan to acquire, the infrastructure or capability internally to develop and manufacture our therapeutic candidates for use in the conduct of our trials or for commercial supply, if our therapeutics are approved. Instead, we rely on, and expect to continue to rely on third-party providers to manufacture the supplies for our preclinical studies and clinical trials. We currently rely on a limited number of third-party contract manufacturers for our required raw materials, antibodies, and other biologics for our preclinical research and clinical trials, as well as for the manufacture of supplies for our therapeutic candidates. To the extent any of our manufacturing partners are unable to fulfill these obligations in a timely manner, our clinical trials may be delayed, and our business may be adversely affected. In general, reliance on third party providers may expose us to more risk than if we were to manufacture our therapeutic candidates ourselves. In addition, the facilities used by our third-party manufacturers must be approved for the manufacture of our therapeutic candidates by the FDA, or any comparable foreign regulatory authority, pursuant to inspections that will be conducted after we submit a BLA to the FDA, or submit a comparable marketing application to a foreign regulatory authority. We do not control the operational processes of the contract manufacturing organizations with whom we contract and are dependent on these third parties for the production of our therapeutic candidates in accordance with relevant regulations (such as cGMP), which include, among other things, quality control and the maintenance of records and documentation.

We rely, in part, on foreign CROs and CMOs, such as WuXi AppTec. Such foreign CROs and CMOs may be subject to U.S. legislation, sanctions, trade restrictions and foreign regulatory requirements which could increase the cost or reduce the supply of material available to us, delay the procurement or supply of such material or have an adverse effect on our ability to secure significant commitments from governments to purchase our potential therapies. For example, the BIOSECURE Act was passed by the House of Representatives in September 2024 and a substantially similar bill is pending in the Senate. If these bills become law, or similar laws are passed, they would have the potential to restrict the ability of U.S. biopharmaceutical companies like us to 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. Such disruption could have adverse effects on the development of our therapeutic candidates if we are unable to find alternative suppliers.

In addition, we have no control over the ability of third-party manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or any comparable foreign regulatory authority does not approve these facilities for the manufacture our therapeutic candidates, or if such authorities withdraw any such approval in the future, we may be required to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our therapeutic candidates, if approved. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, seizures or recalls, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect our financial position.

In addition, we do not have any long-term commitments or supply agreements with any third-party manufacturers. We may be unable to establish any long-term supply agreements with third-party manufacturers or to do so on acceptable terms, which increases the risk of failing to timely obtain sufficient quantities of our therapeutic

candidates or such quantities at an acceptable cost. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- failure of third-party manufacturers to comply with regulatory requirements and maintain quality assurance;
- breach of the manufacturing agreement by the third party;
- failure to manufacture our therapeutic candidates according to our specifications;
- failure to manufacture our therapeutic candidates according to our schedule or at all;
- misappropriation of our proprietary information, including our trade secrets and know-how; and
- termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us.

Any of these occurrences could have a material adverse effect on our business.

Our third-party manufacturers may be unable to successfully scale up manufacturing of our therapeutic candidates in sufficient quality and quantity, which would delay or prevent us from developing our therapeutic candidates and commercializing any approved therapeutic candidates.

Our manufacturing partners may be unable to successfully increase the manufacturing capacity for our therapeutic candidates in a timely or cost-effective manner, or at all, as needed for our development efforts or, if our therapeutic candidates are approved, our commercialization efforts. Quality issues may also arise during scale-up activities. If we, or any manufacturing partners, are unable to successfully scale up the manufacture of our therapeutic candidates in sufficient quality and quantity, the development, testing, and clinical trials of our therapeutic candidates may be delayed or infeasible, and marketing approval or future commercial launch of any resulting therapeutic may be delayed or not obtained, which could significantly harm our business.

Failure to successfully identify, develop and commercialize additional therapeutics or therapeutic candidates could impair our ability to grow.

Although a substantial amount of our efforts will focus on the continued preclinical and clinical testing and potential approval of our therapeutic candidates in our current pipeline, we continue to innovate and expect to expand our portfolio. Because we have limited financial and managerial resources, research programs to identify therapeutic candidates may require substantial additional technical, financial and human resources, whether or not any new potential therapeutic candidates are ultimately identified. Our success may depend in part upon our ability to identify, select and develop promising therapeutic candidates and therapeutics. We may expend resources and ultimately fail to discover and generate additional therapeutic candidates suitable for further development. All therapeutic candidates are prone to risks of failure typical of biotechnology product development, including the possibility that a therapeutic candidate may not be suitable for clinical development as a result of its harmful side effects, limited efficacy or other characteristics indicating that it is unlikely to receive approval by the FDA and other comparable foreign regulatory authorities or to achieve market acceptance. If we do not successfully develop and commercialize new therapeutic candidates we have identified and explored, our business, prospects, financial condition and results of operations could be adversely affected.

Our business entails a significant risk of product liability and our ability to obtain sufficient insurance coverage could have a material and adverse effect on our business, financial condition, results of operations and prospects.

We are exposed to significant product liability risks inherent in the development, testing, manufacturing and marketing of biotechnology treatments of any therapeutic candidates for which we may conduct clinical trials. Product liability claims could delay or prevent completion of our development programs. If we succeed in marketing any approved products, these claims could result in an FDA investigation of the safety and effectiveness of our future commercial products, our manufacturing processes and facilities (or the manufacturing processes and facilities of our third-party manufacturers) or our marketing programs, a recall of our products or more serious enforcement action, limitations on the approved indications for which the product may be used or suspension or withdrawal of approvals. Regardless of the merits or eventual outcome, liability claims may also result in decreased demand for our products, injury to our reputation, costs to defend the related litigation, a diversion of management's time and our resources, substantial monetary awards to clinical trial participants or patients and a decline in our stock price. Any insurance we have or may obtain may not provide sufficient coverage against potential liabilities. Furthermore, clinical trial and product liability insurance is becoming increasingly expensive. As a result, we may be unable to obtain sufficient insurance at a reasonable cost to protect us against losses caused by potential product

liability claims that could have a material and adverse effect on our business, financial condition, results of operations and prospects.

If our therapeutic candidates are approved for marketing and commercialization and we are unable to develop sales, marketing and distribution capabilities on our own or enter into agreements with third parties to perform these functions on acceptable terms, we will be unable to commercialize successfully any such therapeutic candidates.

We currently have no sales, marketing or distribution capabilities. We will need to expand our own internal sales, marketing and distribution capabilities to commercialize our approved therapeutic candidates, if any, in the United States and other worldwide territories, or will need to enter into collaborations with third parties to perform these services. Any internal effort would be expensive and time-consuming, and we would need to commit significant financial and managerial resources to develop an internal marketing and sales force with technical expertise and the related supporting distribution, administration and compliance capabilities. If we were to rely on additional third parties with these capabilities to market our future therapeutics or were to decide to co-promote products with any of our future collaborators, we would need to establish and maintain or revise existing marketing and distribution arrangements with these partners, and there can be no assurance that we will be able to enter into such arrangements on acceptable terms or at all. Any revenue we receive in connection with third-party license, marketing or distribution arrangements, will depend upon the efforts of these third parties, and there can be no assurance these third parties will establish adequate sales and distribution capabilities or be successful in gaining market acceptance of any approved product. If we are not successful in commercializing any product approved in the future, either on our own or through third parties, our business, financial condition, results of operations and prospects could be materially and adversely affected.

The future commercial success of our therapeutic candidates will depend on the degree of market acceptance of our therapeutic candidates among physicians, patients, healthcare payors and the medical community.

Our therapeutic candidates are still in clinical development and our emerging pipeline is still in preclinical development; we may never have an approved product that is commercially successful. Due to the inherent risk in the development of biopharmaceutical products, it is probable that not all or none of the therapeutic candidates in our pipeline, including any that are or may be licensed to third parties, will successfully complete development and be commercialized. Furthermore, even when available on the market, our products may not achieve an adequate level of acceptance by physicians, patients and the medical community, and we may not become profitable. In addition, efforts to educate the medical community and third-party payors on the benefits of our products may require significant resources and may never be successful, which would prevent us from generating significant revenue or becoming profitable. Market acceptance of any approved products by physicians, patients and healthcare payors will depend on a number of factors, many of which are beyond our control, including, but not limited to:

- changes in the standard of care for the targeted indications for any approved product;
- wording in the FDA- or EMA-approved prescribing information;
- sales, marketing and distribution support;
- potential product liability claims;
- acceptance by physicians, patients and healthcare payors of each product as safe, effective and cost-effective;
- relative convenience, ease of use, ease of administration and other perceived advantages over alternative products;
- prevalence and severity of adverse events or publicity;
- limitations, precautions or warnings listed in the summary of product characteristics, patient information leaflet, package labeling or instructions for use;
- the cost of treatment with our therapeutics in relation to alternative treatments;
- the extent to which products are approved for inclusion and adequately reimbursed on formularies of hospitals and third-party payors, including managed care organizations; and
- whether our products are designated in the label, under physician treatment guidelines or under reimbursement guidelines as a first, second, third or last line therapy.

Risks Related to Our Organization and Operations

We face significant competition and if our competitors develop and market products that are more effective, safer or less expensive than the therapeutic candidates we develop, our commercial opportunities will be negatively impacted.

The life sciences industry is highly competitive. We are currently developing therapeutic candidates that will compete, if approved, with other products and therapies that currently exist or are being developed. Our primary competitors fall into the following groups:

- Companies developing novel therapeutics based on sdAb or alternative scaffold product candidates, including Alligator Bioscience AB, Crescendo Biologics Ltd., GlaxoSmithKline plc, Lava Therapeutics N.V., Molecular Partners AG, Precirix NV, and Sanofi;
- Antibody drug discovery companies that may compete with us in the search for novel therapeutic antibody targets, including Regeneron Pharmaceuticals, Inc., Adimab LLC, Genmab A/S, Macrogenics, Inc., Merus N.V., Numab Therapeutics AG, Amgen, Inc., Xencor, Inc., and Zymeworks Inc.; and
- Companies developing therapeutics for the treatment of autoimmune diseases, including Sanofi, Amgen Inc., AstraZeneca plc, F. Hoffmann-La Roche AG, Pfizer Inc., Merck & Co., Inc., Novartis AG, Candid Therapeutics, Inc., Hinge Bio, Inc., and Apogee Therapeutics, Inc.

Our competitors also include other large pharmaceutical and biotechnology companies who may be developing therapeutic candidates with mechanisms similar to or targeting the same indications as our therapeutic candidates.

Products we may develop in the future are also likely to face competition from other products and therapies, some of which we may not currently be aware. We have competitors both in the United States and internationally, including major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical companies, universities and other research institutions. Many of our competitors have significantly greater financial, manufacturing, marketing, product development, technical and human resources than we do. Large pharmaceutical companies, in particular, have extensive experience in clinical testing, obtaining marketing approvals, recruiting patients and manufacturing pharmaceutical products. These companies also have significantly greater research and marketing capabilities than we do and may also have products that have been approved or are in late stages of development, and collaborative arrangements in our target markets with leading companies and research institutions. Established pharmaceutical companies may also invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make the therapeutic candidates that we develop obsolete. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. As a result of all of these factors, our competitors may succeed in obtaining patent protection and/or marketing approval or discovering, developing and commercializing products in our field before we do.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe effects, are more convenient, have a broader label, are marketed more effectively, are reimbursed or are less expensive than any products that we may develop. Our competitors also may obtain FDA or other marketing approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. Even if the therapeutic candidates we develop achieve marketing approval, they may be priced at a significant premium over competitive products if any have been approved by then, resulting in reduced competitiveness.

Smaller and other early stage companies may also prove to be significant competitors. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. In addition, the biopharmaceutical industry is characterized by rapid technological change. If we fail to stay at the forefront of technological change, we may be unable to compete effectively. Technological advances or products developed by our competitors may render our therapeutic candidates obsolete, less competitive or not economical.

Any inability to attract and retain qualified key management and technical personnel would impair our ability to implement our business plan.

Our success largely depends on the continued service of key management, advisors and other specialized personnel, including Mark P. Lappe, our Chief Executive Officer, Brendan P. Eckelman, Ph.D., our Chief Scientific Officer, and Kelly D. Deck, our Chief Financial Officer, who are all employed at will and for whom we do not have "key man" insurance coverage. The loss of one or more members of our management team or other key employees or advisors could delay our research and development programs and have a material and adverse effect on our business, financial condition, results of operations and prospects. We are dependent on the continued service of our technical personnel because of the highly technical nature of our therapeutic candidates and technologies and the specialized nature of the marketing approval process. Our future success will depend in large part on our continued ability to attract and retain other highly qualified scientific, technical and management personnel, as well as personnel with expertise in clinical testing, manufacturing, governmental regulation and commercialization. We face competition for personnel from other companies, universities, public and private research institutions, government entities and other organizations (many of whom have substantially greater financial resources than us), and we might not be able to attract or retain these key employees on conditions that are economically acceptable. Our inability to attract and retain these key employees could prevent us from achieving our objectives and implementing our business strategy, which could have a material adverse effect on our business and prospects.

We have a significant amount of debt which may affect our ability to operate our business and secure additional financing in the future. If we fail to comply with the terms of our loan agreement with Oxford, our business, prospects and results of operations could be materially and adversely affected.

In January 2025, we borrowed a total of $100.0 million from Oxford under a loan and security agreement, or the 2025 Loan Agreement. Our obligations under the 2025 Loan Agreement are secured by substantially all of our assets. The 2025 Loan Agreement requires us, and any debt arrangements or instruments we may enter into in the future may require us, to comply with various covenants that limit our ability to, among other things:

- dispose of assets;
- complete mergers or acquisitions;
- incur or guarantee indebtedness;
- sell or encumber any assets;
- pay dividends or make other distributions to holders of our capital stock, including by way of certain stock buybacks;
- make specified investments;
- engage in different lines of business; and
- engage in certain transactions with our affiliates.

These covenants may limit our flexibility in operating our business. A failure by us to comply with the covenants could result in an event of default, which could adversely affect our business. Upon the occurrence of an event of default, including the occurrence of a material adverse change, the lender could elect to declare all amounts outstanding to be due and payable and exercise other remedies. If the indebtedness were to be accelerated, our future financial condition could be materially adversely affected.

We may incur additional indebtedness in the future. The instruments governing such indebtedness could contain provisions that are as, or more, restrictive than our existing debt instruments. Our obligations pursuant to the 2025 Loan Agreement are secured by substantially all of our assets, including our intellectual property. If we are unable to repay, refinance or restructure our indebtedness when payment is due, the lenders could proceed against this collateral granted to them to secure such indebtedness or force us into bankruptcy or liquidation. Further, if our business is subject to liquidation, the right to repayment of Oxford and any other holders of indebtedness would be senior to the rights of the holders of our common stock to receive any proceeds from the liquidation.

We are subject to continuing contingent liabilities of the Former Parent following the Separation and Distribution.

There are several significant areas where the liabilities of the Former Parent may become our obligations, notwithstanding the Separation and Distribution. For example, under the Internal Revenue Code of 1986, as

amended, or the Code, and the related rules and regulations, each corporation that was a member of the Former Parent's consolidated U.S. federal income tax reporting group during any taxable period or portion of any taxable period ending on or before the effective time of the Distribution is jointly and severally liable for the U.S. federal income tax liability of the entire Former Parent consolidated tax reporting group for that taxable period. In addition, the Separation and Distribution Agreement, dated as of January 22, 2024, by and among the Former Parent, the Company and Aventis, Inc., a Pennsylvania corporation, or the Separation and Distribution Agreement, allocates the responsibility for taxes between the Former Parent and us. Pursuant to this allocation, we may be responsible for taxes that we would not have otherwise incurred, or that we would have incurred but in different amounts or at different times, on a standalone basis outside of the Former Parent consolidated group, and the amount of such taxes could be significant. If the Former Parent is unable to pay any prior period taxes for which it is responsible, we could be required to pay the entire amount of such taxes.

We are required to pay Former Parent for certain tax savings we may realize as a result of the Code Section 336(e) election made in connection with the Distribution.

The Company and the Former Parent made a joint election under Section 336(e) of the Code and the applicable Treasury Regulations thereunder with respect to the Distribution, or the Section 336(e) Election. As a result of the Section 336(e) Election, for U.S. federal income tax purposes, the Company's assets were generally deemed to have been sold in a taxable sale, which gave rise to a related step-up in the tax basis of such assets existing at the time. The Separation and Distribution Agreement requires the Company to make annual payments to the Former Parent equal to 85 percent of the Company's actual cash tax savings, as and when realized, from such step-up in tax basis, or the Realized Tax Benefit. The calculation of Realized Tax Benefits is determined based on various assumptions set forth in the Separation and Distribution Agreement and in certain cases may exceed the actual cash tax savings the Company realizes. The payments that we may be required to make under the Separation and Distribution Agreement could be substantial.

Use of any net operating loss carryforwards and other tax attributes may be limited.

We anticipate that we will incur significant losses for the foreseeable future. Our ability to utilize net operating loss, or NOL, carryforwards and certain other tax attributes (if any) to offset future taxable income or tax liabilities (if any) may be limited as a result of ownership changes. Under Sections 382 and 383 of the Code, a corporation that undergoes an "ownership change" may be subject to limitations on its ability to utilize its pre-change NOLs and other tax attributes otherwise available to offset future taxable income and/or tax liability. An ownership change is generally defined as a cumulative change of 50 percentage points or more in the ownership positions of certain stockholders or groups of stockholders during a rolling three-year period. It is possible that the Company may experience ownership changes in the future as a result of shifts in our stock ownership (some of which shifts are outside our control). Corresponding rules may apply under state tax laws. Even if there is no limitation on utilization of our NOL carryforwards as the result of an ownership change, utilization of NOL carryforwards is limited and may reduce taxable income by no more than 80% of the pre-NOL taxable income in such year. If we earn taxable income in a future year, such limitations on utilization of NOL carryforwards could result in increased future tax liability to us and our future cash flows could be adversely affected. Additionally, we use our best judgment in attempting to quantify and reserve for these tax obligations. However, a challenge by a taxing authority, our ability to utilize tax benefits such as carryforwards or tax credits, or a deviation from other tax-related assumptions may cause actual financial results to deviate from previous estimates.

Our employees, independent contractors, principal investigators, contract research organizations, consultants or vendors may engage in misconduct or other improper activities, including non-compliance with governmental and regulatory bodies.

We are exposed to the risk of fraud or other misconduct by our employees, independent contractors, principal investigators, contract research organizations, consultants or vendors. Misconduct by these parties could include intentional failures to comply with state and federal securities laws, FDA regulations, provide accurate information to the FDA, comply with manufacturing standards we may establish for our therapeutic candidates, comply with federal and state data privacy, security, fraud and abuse, and other healthcare laws and regulations, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud,

kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Activities subject to these laws could also involve the improper use or misrepresentation of information obtained in the course of clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. 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 or regulations. Additionally, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. 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 material and adverse effect on our business, financial condition, results of operations and prospects, including the imposition of significant civil, criminal and administrative penalties, monetary damages, fines, disgorgement, imprisonment, loss of eligibility to obtain marketing approvals from the FDA, exclusion from participation in government contracting, healthcare reimbursement or other government programs, including Medicare and Medicaid, reputational harm, diminished profits and future earnings, additional reporting requirements if subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with any of these laws, and the curtailment or restructuring of our operations.

Our insurance may not provide adequate levels of coverage against claims which may adversely affect our financial condition.

We maintain insurance that we believe is adequate for businesses of our size and type. However, there are types of losses that we believe are not economically reasonable to insure or that cannot be insured against. For instance, because directors and officers, or D&O, liability insurance has become cost prohibitive with high retentions providing minimal coverage, we have not renewed our D&O policy.

It is possible that we may be subject to securities litigation in the future, including potential class action or stockholder derivative actions. Our indemnification agreements with our directors and certain officers, as well as Delaware General Corporation Law, or DGCL, may require us, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. Without D&O insurance, the amounts we would pay to defend any such litigation or indemnify our officers and directors should they be subject to legal action based on their service to us could have a material adverse effect on our financial condition, results of operations and liquidity.

As we expand our development and regulatory capabilities, we may encounter difficulties in managing our growth, which could disrupt our operations.

We may experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of drug development and regulatory affairs, as well as sales and marketing to the extent any of our therapeutic candidates approach receipt of marketing authorization. To manage our future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

We may not be able to integrate efficiently or achieve the expected benefits of any acquisitions of complementary businesses, therapeutic candidates or technologies.

Should we in the future acquire any complementary business, therapeutic candidates or technologies, our ability to integrate and manage acquired businesses, therapeutic candidates or technologies effectively will depend upon a number of factors including the size of the acquired business, the complexity of any therapeutic candidate or technology and the resulting difficulty of integrating the acquired business's operations, if any. Our relationship with current employees or employees of any acquired business may become impaired. We may also be subject to unexpected claims and liabilities arising from such acquisitions. These claims and liabilities could be costly to defend, could be material to our financial condition and might exceed either the limitations of any applicable indemnification provisions or the financial resources of the indemnifying parties. There can also be no assurance

that we will be able to assess ongoing profitability and identify all actual or potential liabilities of a business, therapeutic candidate or technology prior to its acquisition. If we acquire businesses, therapeutic candidates or technologies that result in assuming unforeseen liabilities in respect of which it has not obtained contractual protections or for which protection is not available, this could materially adversely affect our business, prospects, financial condition and results of operations.

Our business may be adversely affected as a result of major computer system failures.

Any of the internal computer systems belonging to us or our third-party service providers are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war, and telecommunication and electrical failure. Any system failure, accident or security breach that causes interruptions in our own or in third-party service vendors' operations could result in a material disruption of our development programs. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our or our partners' marketing approval efforts and significantly increase our costs in order to recover or reproduce the lost data. To the extent that any disruption or security breach results in a loss or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we may incur liability, our development programs, reputation and competitive position may be adversely affected and the further development of our therapeutic candidates may be delayed. Furthermore, we may incur additional costs to remedy the damage caused by these disruptions or security breaches.

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

We maintain sensitive company data on our computer networks and third-party cloud services, including our intellectual property and proprietary business information. We face a number of threats to our networks from unauthorized access, accidental acts or omissions that expose vulnerabilities, security breaches and other system disruptions. Our third-party partners, including CROs and providers of data hosting or cloud services, as well as suppliers, distributors, alliances, and other third-party service providers, face similar risks, which could affect us directly or indirectly.

We are increasingly dependent upon our technology systems to operate our business and our ability to effectively manage our business depends on the security, reliability and adequacy of our technology systems and data, which includes use of cloud technologies. A breakdown, invasion, corruption, destruction or breach of our technology systems, including the cloud technologies that we utilize, and/or unauthorized access to our data and information could subject us to liability or negatively impact the operation of our business. Our technology systems, including the cloud technologies that we utilize, continue to increase in multitude and complexity, making them potentially vulnerable to breakdown, malicious intrusion and random attack. Likewise, data privacy or security breaches by individuals authorized to access our technology systems, including the cloud technologies that we utilize, may pose a risk that sensitive data, including intellectual property, trade secrets, personal information or preclinical or clinical trial data belonging to us, our clinical trial participants, or other business partners, may be exposed to unauthorized persons or to the public.

Cyberattacks are increasing in their frequency, sophistication and intensity, and are becoming increasingly difficult to detect. They are often carried out by motivated, well-resourced, skilled and persistent actors, including nation states, organized crime groups, "hacktivists" and employees or contractors acting with malicious intent. Cyberattacks could include the deployment of harmful malware and key loggers, ransomware, a denial-of-service attack, a malicious website, the use of social engineering and other means to affect the confidentiality, integrity and availability of our technology systems and data. Our key business partners face similar risks and any security breach of their systems could adversely affect our security posture. In addition, our increased use of cloud technologies could heighten these and other operational risks, and any failure by cloud technology service providers to adequately safeguard their systems and prevent cyber-attacks could disrupt our operations and result in misappropriation, corruption, or loss of confidential or propriety information.

The United States federal and all state and foreign governments have adopted or proposed requirements regarding the collection, distribution, use, security, and storage of personally identifiable information and other data relating to individuals, and federal and state consumer protection laws are being applied to enforce regulations related to the

collection, use, and dissemination of data. Some of these federal, state and foreign government requirements include obligations of companies to notify individuals and others of security breaches involving certain personally identifiable information, which could result from breaches experienced by us or by our vendors, contractors, or organizations with which we have formed strategic relationships. Even though we may have contractual protections with such vendors, contractors, or other organizations, notifications and follow-up actions related to a security breach could impact our reputation, prompt regulatory scrutiny and enforcement, cause us to incur significant costs, including legal expenses, or cause us to incur remediation costs that could, under such circumstances, materially harm our business.

Any such security breach may materially compromise information stored on our networks and may result in significant data losses or theft of our intellectual property or proprietary business information, it may also subject us to significant fines, penalties or liabilities for any noncompliance with certain privacy and security laws. We maintain cyber liability insurance; however, this insurance may not be sufficient to cover the financial, legal, business, or reputational losses that may result from an interruption of breach of our systems.

While we continue to build and improve our systems and infrastructure, including our business continuity plans, there can be no assurance that our efforts will prevent breakdowns or breaches in our systems that could adversely affect our business and operations and/or result in the loss of critical or sensitive information, which could result in financial, legal, business, operational or reputational harm to us, loss of competitive advantage or loss of consumer confidence. For example, the loss of clinical trial data from completed or ongoing clinical trials could result in delays in our development and regulatory approval efforts and significantly increase our costs to recover or reproduce the data. In addition, our liability insurance may not be sufficient in type or amount to cover us against claims related to security breaches, cyber-attacks and other related breaches. Further, a data breach could result in regulatory investigations and negative publicity which could damage our reputation and have an adverse effect on our business, financial condition or results of operations.

Our current operations are concentrated in one location, and we or the third parties upon whom we depend may be adversely affected by earthquakes, medical epidemics or pandemics, or other natural disasters.

Our current operations are located in our facilities in La Jolla, California. Any unplanned event, such as flood, fire, explosion, earthquake, extreme weather condition, medical epidemics or pandemics, power shortage, telecommunication failure or other natural or man-made accidents or incidents, that results in us being unable to fully utilize our facilities, or the manufacturing facilities of our third-party contract manufacturers, may have a material and adverse effect on our ability to operate our business, particularly on a daily basis, and have significant negative consequences on our financial and operating conditions. Loss of access to these facilities may result in increased costs, delays in the development of our therapeutic candidates or interruption of our business operations. Earthquakes, medical epidemics or pandemics or other natural disasters could further disrupt our operations, and have a material and adverse effect on our business, financial condition, results of operations and prospects. Certain of these natural disasters, including fires and severe weather events may be exacerbated by the effects of climate change. If a natural disaster, pandemic, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as our research facilities or if similar events occurred elsewhere effecting the manufacturing facilities of our third-party contract manufacturers, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible, for us to continue our business for a substantial period of time. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which, could have a material and adverse effect on our business. As part of our risk management policy, we maintain insurance coverage at levels that we believe are appropriate for our business. However, in the event of an accident or incident at these facilities, we cannot assure you that the amounts of insurance will be sufficient to satisfy any damages and losses. If our facilities, or the manufacturing facilities of our third-party contract manufacturers, are unable to operate because of an accident or incident or for any other reason, even for a short period of time, any or all of our research and development programs may be harmed. Any business interruption may have a material and adverse effect on our business, financial condition, results of operations and prospects.

Risks Related to Intellectual Property

If we are not able to obtain and enforce intellectual property protection for our technologies or therapeutic candidates, the development and commercialization of our therapeutic candidates may be adversely affected.

Our success depends, in part, on our ability to obtain, maintain, and enforce our intellectual property rights. We rely on a combination of patents, trademarks, and trade secrets to protect our current and future therapeutic candidates and methods for treating patients using our therapeutic candidates. Our patent portfolio includes various issued United States patents, United States pending non-provisional patent applications, United States pending provisional applications, pending Patent Cooperation Treaty, or PCT, applications, issued foreign patents, and foreign patent applications currently pending in various foreign jurisdictions.

While we will endeavor to protect our therapeutic candidates with intellectual property rights such as patents, as appropriate, the process of obtaining, maintaining, and enforcing patents is time-consuming, expensive and sometimes unpredictable, and we may not be able to file and prosecute all necessary or desirable patent applications, or maintain and enforce any patents that may issue from such 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 before it is too late to obtain patent protection. The patent applications that we own or may in-license may fail to result in issued patents, and, even if they do issue as patents, such patents may not cover our current or future technologies or product candidates in the United States or in other countries or provide sufficient protection from competitors. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. We may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the rights to any patents we may license to or from third parties. Therefore, such patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business.

Our existing issued and granted patents and any future patents we obtain may not be sufficiently broad to prevent others from using our technology or from developing competing products and technology. There is no guarantee that any of our pending patent applications will result in issued or granted patents, that any of our issued or granted patents will not later be found to be invalid or unenforceable or that any issued or granted patents will include claims that are sufficiently broad to provide meaningful protection from any competitors. Our competitors may be able to circumvent our patents by developing similar or alternative therapeutic candidates in a non-infringing manner. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our current and future proprietary technology and therapeutic candidates are covered by valid and enforceable patents or are effectively maintained as trade secrets. If third parties disclose or misappropriate our proprietary rights, it may materially and adversely affect our business.

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process. There are situations in which non-compliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case. The standards applied by the USPTO and foreign patent offices in granting patents are not always applied uniformly or predictably. For example, there is no uniform worldwide policy regarding patentable subject matter or the scope of claims allowable in biotechnology patents. As such, we do not know the degree of future protection that we will have on our proprietary therapeutics and technology.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal, technological and factual questions and has in recent years been the subject of much litigation. Once granted, patents may remain open to opposition, interference, re-examination, post-grant review, inter partes review, nullification or derivation action in court or before patent offices or similar proceedings for a given period after allowance or grant, during which time third parties can raise objections against such initial grant. In the course of such proceedings, which may continue for a protracted period of time, the patent owner may be compelled to limit the scope of the allowed or granted claims thus attacked, or may lose the allowed or granted claims altogether, e.g., due to a determination that the claims are invalid or unenforceable. In addition, there can be no assurance that:

- others will not or will not be able to legally make, use or sell products or therapeutic candidates that are the same as or similar to our therapeutic candidates despite the claims of the patents that we own or license;
- we or our licensors are the first to make the inventions covered by each of our issued patents and pending patent applications that we own or license;
- we or our licensors are the first to file patent applications covering certain aspects of our inventions;
- others will not independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- any issued patents that we own or have licensed will provide us with any competitive advantage; or
- the patents of others will not have a material or adverse effect on our business, financial condition, results of operations and prospects.

As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain.

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

Obtaining valid and enforceable issued or granted patents covering our therapeutic candidates in the United States and worldwide can be extremely costly. In jurisdictions where we have not obtained patent protection, competitors or third parties may use our technology to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but where it is more difficult to enforce a patent as compared to the United States. Third-party or competitor products may compete with our future products in jurisdictions where we do not have issued or granted patents or where our issued or granted patent claims or other intellectual property rights are not sufficient to prevent competitor activities in these jurisdictions. The legal systems of certain countries, particularly certain developing countries, make it difficult to enforce patents and such countries may not recognize other types of intellectual property protection, particularly that relating to biotechnology. This could make it difficult for us to prevent the infringement of our patents or marketing of competing products in violation of our proprietary rights generally in certain jurisdictions. Proceedings to enforce our patent rights in foreign jurisdictions could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing, could provoke third parties to assert claims against us, and, whether or not successful, could result in substantial cost and divert our efforts and attention from other aspects of our business.

We generally file a provisional patent application first (a priority filing) at the USPTO. An international application under the PCT is usually filed within 12 months after the priority filing. Based on the PCT filing, national and regional patent applications may be filed in the United States, Europe, Japan, Australia and Canada and, depending on the individual case, also in one, several or all of Brazil, China, India, Israel, Mexico, New Zealand, Russia or Eurasian Patent Organization, Singapore, South Africa, South Korea and other jurisdictions. We have so far not filed for patent protection in all national and regional jurisdictions where such protection may be available. In addition, we may decide to abandon national and regional patent applications before grant. Finally, the grant proceeding of each national or regional patent is an independent proceeding which may lead to situations in which applications might in some jurisdictions be refused by the relevant registration authorities, while granted by others. It is also quite common that, depending on the country, various scopes of patent protection may be granted on the same therapeutic candidate or technology.

When a patent is granted by a regional patent office (e.g., Europe or Eurasia), the patent must be validated in individual countries in order to be in effect in those countries. We may decide not to validate regional patents in every available country or at all in any country in the region. In addition, we may decide to abandon national and regional patent applications before or after grant.

The laws of some jurisdictions do not protect intellectual property rights to the same extent as the laws in the United States, and many companies have encountered significant difficulties in protecting and defending such rights in such jurisdictions. If we or any licensors encounter difficulties in protecting, or are otherwise precluded from effectively protecting, the intellectual property rights important for our business in such jurisdictions, the value of these rights may be diminished and we may face additional competition from others in those jurisdictions. 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 licensors are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position in the relevant jurisdiction may be impaired and our business and results of operations may be adversely affected.

Moreover, geopolitical actions in the U.S. and in foreign countries could increase the uncertainties and costs surrounding the prosecution or maintenance of our patent applications or those of any current or future licensors and the maintenance, enforcement or defense of our issued patents or those of any current or future licensors. For example, the U.S. and foreign government actions related to Russia's conflict in Ukraine may limit or prevent filing, prosecution, and maintenance of patent applications in Russia. Government actions may also prevent maintenance of issued patents in Russia. These actions could result in abandonment or lapse of our patents or patent applications, resulting in partial or complete loss of patent rights in Russia. In addition, a decree was adopted by the Russian government in March 2022, allowing Russian companies and individuals to exploit inventions owned by patentees from the U.S. without consent or compensation. Consequently, we would not be able to prevent third parties from practicing our inventions in Russia or from selling or importing products made using our inventions in and into Russia. Accordingly, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.

Changes in patent laws 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 and other jurisdictions in which we file patent applications could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. For example, under the Leahy-Smith America Invents Act, or the America Invents Act, enacted in September 2011, the United States transitioned to a first inventor to file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application is entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. In contrast, prior to March 2013, in the United States, the first to invent the claimed invention was entitled to the patent, assuming that other requirements for patentability were met. Furthermore, United States patent law under the America Invents Act allows for post issuance challenges to United States patents, including ex parte reexaminations, inter parte reviews and post grant oppositions. If our United States patents are challenged using such procedures, we may not prevail, possibly resulting in altered or diminished claim scope or loss of patent rights altogether. Similarly, some countries, notably members of the European Union, also have post grant opposition proceedings that can result in changes in scope and/or cancellation of patent claims.

The United States Supreme Court has also ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the United States Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

In addition, the United States federal government retains certain rights in inventions produced with its financial assistance under the Patent and Trademark Law Amendments Act, or the Bayh-Dole Act. The federal government retains a "nonexclusive, nontransferable, irrevocable, paid-up license" for its own benefit. The Bayh-Dole Act also provides federal agencies with "march-in rights." March-in rights allow the government, in specified circumstances, to require the contractor or successors in title to the patent to grant a "nonexclusive, partially exclusive, or exclusive license" to a "responsible applicant or applicants." If the patent owner refuses to do so, the government may grant the license itself. If, in the future, we co-own or license in technology which is critical to our business that is developed in whole or in part with federal funds subject to the Bayh-Dole Act, our ability to enforce or otherwise exploit patents covering such technology may be adversely affected.

As another example, the complexity and uncertainty of European patent laws have increased in recent years. In Europe, a new unitary patent system was launched on June 1, 2023, which significantly impacted European patents,

including those granted before the introduction of such a system. Under the unitary patent system, European applications now have the option, upon grant of a patent, of becoming a Unitary Patent, which are subject to the jurisdiction of the Unitary Patent Court, or UPC. As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any litigation. Patents granted before the implementation of the UPC have the option of opting out of the jurisdiction of the UPC and remaining as national patents in the UPC countries. Patents that remain under the jurisdiction of the UPC will be potentially vulnerable to a single UPC-based revocation challenge that, if successful, could invalidate the patent in all countries who are signatories to the UPC. We have opted our current European patents and patent applications out of the UPC and may opt out our future European patents and patent applications. However, if certain formalities and requirements for opting-out are not met, our current or future European patents could be subject to the jurisdiction of the UPC. We may decide to opt out certain European patents and patent applications from the UPC. However, if certain formalities and requirements for opting-out are not met, our current or future European patents could be subject to the jurisdiction of the UPC. While we have the right to opt our patents out of the UPC over the first seven years of the court's existence, doing so may preclude us from realizing the benefits of the UPC. Moreover, the decision whether to opt-in or opt-out of Unitary Patent status will require coordinating with co-applicants, if any, adding complexity to any such decision. We cannot predict with certainty the long-term effects of any potential changes.

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

The USPTO, the European Patent Office and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. For example, periodic maintenance and annuity fees on any issued patent are due to be paid to the USPTO, the European Patent Office and foreign patent agencies in several stages over the lifetime of the patent. Some jurisdictions also require payment of annuity fees during pendency of a patent application. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we or our licensors fail to maintain the patents and patent applications covering our therapeutic candidates, our competitors might better be able to enter the market, which would have an adverse effect on our business.

We may be required to reduce the scope of our intellectual property due to intellectual property claims included in the patents or patent applications of others.

Third parties may have filed, and may in the future file, patent applications covering technology similar to ours. It is also possible that we have failed to identify relevant third-party patents or applications. For example, United States applications filed before November 29, 2000 and certain United States applications filed after that date that will not be filed outside the United States remain confidential until patents issue. Patent applications in the United States and elsewhere are published approximately 18 months after the earliest filing for which priority is claimed, with this earliest filing date being commonly referred to as the priority date. Therefore, patent applications covering our therapeutic candidates could have been filed by others without our knowledge. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover any future approved products or our therapeutic candidates. Any such patent application may have priority over our patent applications, which could further require us to obtain rights to issued patents covering such technologies, if possible, or block us from practicing certain aspects of our technology if we are unable to successfully pursue litigation to nullify or invalidate the third-party intellectual property right concerned.

If another party has filed a United States patent application on inventions similar to ours that claims priority to an application filed prior to March 16, 2013, we may have to participate in an interference proceeding declared by the USPTO to determine priority of invention in the United States. Similarly, if another party has filed a United States patent application on inventions similar to ours that claims priority to an application filed after March 16, 2013, we may have to participate in a derivation proceeding to determine whether that party derived the claimed invention from an inventor listed on our application and then filed the third-party application without authorization. The costs

of these proceedings could be substantial, and it is possible that such efforts would be unsuccessful if, unbeknownst to us, the other party had independently arrived at the same or similar invention prior to our own invention, resulting in a loss of our United States patent position with respect to such inventions. In addition, an unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms or at all, or if a non-exclusive license is offered and our competitors gain access to the same technology. Further, changes enacted on March 15, 2013 to the United States patent laws under the America Invents Act resulted in the United States changing from a "first to invent" country to a "first to file" country. As a result, we may lose the ability to obtain a patent if a third party files with the USPTO first and could become involved in proceedings before the USPTO to resolve disputes related to inventorship. We may also become involved in similar proceedings in other jurisdictions.

We or our licensors, licensees or any future strategic partners may become subject to third-party claims or litigation alleging infringement of patents or other proprietary rights or seeking to invalidate patents or other proprietary rights, and we may need to resort to litigation to protect or enforce our patents or other proprietary rights, all of which could be costly, time consuming, delay or prevent the development and commercialization of our therapeutic candidates, or put our patents and other proprietary rights at risk.

Our commercial success depends in part on our ability to develop, manufacture, market and sell our current and any future therapeutic candidates and use our proprietary technologies without infringing, misappropriating or otherwise violating the proprietary rights and intellectual property of third parties. Numerous United States and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are pursuing development candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that we may be subject to claims of infringement of the patent rights of third parties. We or our licensors, licensees or any future strategic partners may in the future become party to, or be threatened with, adversarial proceedings or litigation by third parties regarding intellectual property rights with respect to our current and any future therapeutic candidates and technology, including interference proceedings, post grant review and inter partes review before the USPTO or similar proceedings before corresponding foreign patent offices. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our current or future therapeutic candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. There is a risk that third parties may choose to engage in litigation with us to enforce or to otherwise assert their patent rights against us. Even if we or our licensors, licensees or any future strategic partners believe such claims are without merit, a court of competent jurisdiction could hold that these third-party patents are valid, enforceable and infringed, which could have a negative impact on our ability to commercialize our current and any future therapeutic candidates. Moreover, given the vast number of patents in our field of technology, we cannot be certain that we do not infringe existing patents or that we will not infringe patents that may be granted in the future. While we may decide to initiate proceedings to challenge the validity of these or other patents in the future, we may be unsuccessful, and courts or patent offices in the United States and abroad could uphold the validity of any such patent. In order to successfully challenge the validity of any such U.S. patent in federal court, we would need to overcome a presumption of validity. As this is a high burden and requires us to present clear and convincing evidence as to the invalidity of any such U.S. patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent.

If we were to initiate legal proceedings against a third party to enforce a patent covering one of our products or our technology, the defendant could counterclaim that our patent is invalid or unenforceable. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, for example, 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. The outcome following legal assertions of invalidity and unenforceability during patent litigation is unpredictable. For example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. 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. If a defendant 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 one or more of our products or certain aspects of our technology. This loss of patent protection could have a material and adverse effect on our business, financial condition, results of operations and prospects. Patents and other intellectual property rights also will not protect our technology if competitors design around our protected technology without legally infringing our patents or other intellectual property rights. Moreover, we may face patent infringement claims from nonpracticing entities that have no relevant product revenue and against whom our own patent portfolio may thus have no deterrent effect. If a patent infringement suit were threatened or brought against us, we could be forced to stop or delay research, development, manufacturing or sales of the product or product candidate that is the subject of the actual or threatened suit.

If we, our licensees or our licensors, or any future strategic partners are found to infringe a third-party patent or other intellectual property rights, we could be required to pay damages, potentially including treble damages, if we are found to have willfully infringed. In addition, we, our licensees or our licensors, or any future strategic partners may choose to seek, or be required to seek, a license from a third party, which may not be available on acceptable terms, if at all. Even if a license can be obtained on acceptable terms, the rights may be non-exclusive, which could give any competitors access to the same technology or intellectual property rights licensed to us. If we fail to obtain a required license, the holders of any such patents may be able to block us or our licensees from marketing therapeutic candidates based on our technology until such patents expire, which could limit our ability to generate revenue or achieve profitability and possibly prevent us from generating revenue sufficient to sustain our operations. The cost to us in defending or initiating any litigation or other proceeding relating to patent or other proprietary rights, even if resolved in our favor, could be substantial, and litigation would divert our management's attention. Competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could delay our research and development efforts and limit our ability to continue our operations.

Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business, financial condition, results of operations and prospects.

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

We are a party to license agreements under which we are granted rights to third-party intellectual property, and we expect that we may need to enter into additional license agreements in the future. License agreements may impose various development obligations, payment of royalties and fees based on achieving certain milestones, as well as other obligations. If we fail to comply with our obligations under these agreements, the licensor may have the right to terminate the license. The termination of any license agreements or failure to adequately protect such license agreements could prevent us from commercializing therapeutic candidates covered by the licensed intellectual property or otherwise adversely affect our business. Our license agreements may involve sublicenses from third parties which are not the original licensor of the intellectual property at issue. Under these agreements, we would rely on our licensor to comply with its obligations under the primary license agreements, where we may have no relationship with the original licensor of such rights. If the licensors fail to comply with their obligations under these upstream license agreements, the original third-party licensor may have the right to terminate the original license, which may terminate the sublicense. If this were to occur, we would no longer have rights to the applicable intellectual property and, in the case of a sublicense, if we were not able to secure our own direct license with the owner of the relevant rights, which we may not be able to do at a reasonable cost or on reasonable terms, it may adversely affect our ability to continue to develop and commercialize any of our therapeutic candidates incorporating the relevant intellectual property.

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 any collaboration relationships we might enter into in the future;

- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us; and
- the priority of invention of patented technology.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain any licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected therapeutic candidates.

Our intellectual property agreements with our licensors, licensees, and third parties may be subject to disagreements over contract interpretation, which could narrow the scope of, or result in termination of, our rights to the relevant intellectual property or technology or increase our financial or other obligations to such third parties, or reduce the financial or other obligations our licensees have to us.

Certain provisions in our intellectual property agreements may be susceptible to multiple interpretations. For example, we may disagree with our licensors or licensees regarding whether, when and to what extent various obligations under these agreements apply to certain of our/their therapeutic candidates and products, including various payment, development, commercialization, funding, diligence, sublicensing, insurance, patent prosecution and enforcement and/or other obligations. The resolution of any contract interpretation disagreement that may arise could affect the scope of our rights to the relevant intellectual property or technology, or affect financial or other obligations under the relevant agreement. In either case, such disagreement could have a material adverse effect on our business, financial condition, results of operations and prospects.

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. Our assignment agreements may not be self-executing or may be breached, and we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property.

Intellectual property litigation could cause us to spend substantial resources and distract our personnel from their normal responsibilities.

Litigation or other legal proceedings relating to intellectual property claims, with or without merit, are unpredictable, generally expensive, time consuming and are likely to divert significant resources from our core business, including distracting our technical and management personnel from their normal responsibilities. For example, although we were successful in the trade secrets case brought by I-Mab Biopharma, we were required to expend resources litigating and settling the case. 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. 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 adequately conduct such litigation or proceedings. 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. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating or from successfully challenging our intellectual property rights. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material and adverse effect on our ability to compete in the marketplace.

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

In addition to seeking patent protection for certain aspects of our therapeutic candidates, we also consider trade secrets, including confidential and unpatented know-how important to our business. We rely on trade secrets or confidential know-how to protect our technology, especially where patent protection is believed to be of limited value. Trade secrets and confidential know-how are difficult to maintain as confidential. We seek to protect trade secrets and confidential and unpatented know-how, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to such knowledge, such as our employees, partners, 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 under which they are obligated to maintain confidentiality and to assign their inventions to us. 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. Our assignment agreements may not be self-executing or may be breached, and we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property. We may need to share our proprietary information, including trade secrets, with our current and future business partners, collaborators, contractors and others located in countries at heightened risk of theft of trade secrets, including through direct intrusion by private parties or foreign actors, and those affiliated with or controlled by state actors. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. The failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

Moreover, even if relevant agreements are entered into, despite these efforts, any of these parties may breach the agreements and unintentionally or willfully disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Confidentiality agreements may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. 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 in the United States and certain foreign jurisdictions 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, we would have no right to prevent them from using that technology or information to compete with us. Moreover, a competitor who independently develops substantially equivalent proprietary information may even apply for patent protection in respect of the same. If successful in obtaining such patent protection, our competitors could limit our use of our trade secrets or confidential know-how. Under certain circumstances, we may also decide to publish some know-how to attempt to prevent others from obtaining patent rights covering such know-how. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret.

We may be subject to claims that we or our employees or consultants have wrongfully used or disclosed alleged trade secrets or confidential information of our employees' or consultants' former employers or their clients. These claims may be costly to defend and if we do not successfully do so, we may be required to pay monetary damages and may lose valuable intellectual property rights or personnel.

Many of our employees were previously employed at universities or biotechnology companies, including 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 these individuals or we have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer. We have in the past and may again be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers or clients, or our competitors. Litigation has been and may again be necessary to defend against such claims. If we fail in defending such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. A loss of key research personnel or their work product could hamper our ability to commercialize, or prevent us from commercializing, our therapeutic candidates, which could

severely harm our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

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.

Our trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. Our trademarks may not be approved by one or more governmental trademark offices or may not be approved for use on our products by regulatory agencies, such as the FDA. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected.

If our patent terms expire before or soon after our therapeutic candidates are approved, or if manufacturers of biosimilar drugs successfully challenge our patents, our business may be materially harmed.

Patents have a limited duration. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest United States non provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our therapeutic candidates, their manufacture, or use are obtained, once the patent life has expired, we may be open to competition from competitive medications, including biosimilar medications.

Depending upon the timing, duration and conditions of FDA marketing approval of our therapeutic candidates, one or more of our United States patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act, and similar legislation in the European Union. The Hatch-Waxman Act permits a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. The patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, and only one patent applicable to an approved drug may be extended. However, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for that product will be shortened and our competitors may obtain approval to market competing products sooner than we expect. Also, the scope of our right to exclude during any patent term extension period may be limited or may not cover a competitor's product or product use. As a result, our revenue from applicable therapeutic candidates, if approved, could be reduced, possibly materially.

Given the amount of time required for the development, testing and regulatory review of new drug candidates, patents protecting such drug candidates might expire before or shortly after such drug candidates are commercialized. As a result, our patents and patent applications may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. If we are unable to obtain an exclusive license to any such third-party co-owners' interest in such patents or patent applications, such co-owners may be able to license their 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 any such co-owners of our patents 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.

Manufacturers of biosimilar drugs may challenge the scope, validity, or enforceability of our patents in court or before a patent office, and we may not be successful in enforcing or defending those intellectual property rights and, as a result, may not be able to develop or market the relevant product exclusively, which would have a material adverse effect on any potential sales of that product. Upon the expiration of our issued patents or patents that may issue from our pending patent applications, we will not be able to assert such patent rights against potential competitors and our business, financial condition, results of operations, and prospects may be adversely affected.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

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 nor permit us to maintain our competitive advantage. The following examples are illustrative:

- Others may be able to make therapeutic candidates that are the same as or similar to our therapeutic candidates but that are not covered by the claims of the patents that we own or may have exclusively licensed;
- Others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- 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; and
- We may not develop additional technologies that are patentable.

Risks Related to Government Regulation

We may be unable to obtain marketing approval for any product that we may develop and the marketing approval processes of the FDA and other comparable regulatory authorities outside the United States are lengthy, time-consuming and inherently unpredictable.

Any product that we may attempt to develop, manufacture or market in the United States will be subject to extensive regulation by the FDA, including regulations relating to development, preclinical testing, performance of clinical trials, manufacturing and post-approval commercialization. Preclinical testing, clinical trials and manufacturing, among other activities, will be subjected to an extensive review process before a new therapeutic product may be sold in the United States. Satisfaction of these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays. The time required to obtain FDA approval, and any other required approvals for biological products is unpredictable but typically requires several years and may never be obtained.

Any product that we may wish to develop, manufacture or market in countries other than the United States will also be subject to numerous foreign regulatory requirements governing the conduct of clinical trials, manufacturing and marketing, pricing and third-party reimbursement among other things in such countries. The foreign marketing approval process includes all of the risks and uncertainties associated with FDA approval described above as well as risks attributable to the satisfaction of local regulations in such foreign jurisdictions.

In particular, obtaining marketing approval for biological products requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the therapy candidate's safety and efficacy, or with respect to biological products in the United States, such therapeutic candidate's safety, purity and potency. Securing marketing approval also requires the submission of information about the product manufacturing process, and in many cases the inspection of manufacturing, processing, and packaging facilities by the regulatory authorities. Our therapeutic candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use, or there may be deficiencies in cGMP or similar foreign requirements compliance by us or by our contract development and manufacturing organizations, or CDMOs, that could result in the candidate not being approved. Moreover, we have not obtained marketing approval for any therapeutic candidate in any jurisdiction and it is possible that none of our existing therapeutic candidates or any therapeutic candidates we may seek to develop in the future will ever obtain marketing approval.

Our therapeutic candidates could fail to receive, or could be materially delayed in receiving, marketing approval for many reasons, including any one or more of the following:

- the FDA, EMA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA, EMA or comparable foreign regulatory authorities that a therapeutic candidate is safe, pure, potent and/or effective for its proposed indication;

- the results of clinical trials may not meet the level of statistical significance required by the FDA, EMA or comparable foreign regulatory authorities for marketing approval;
- we may be unable to demonstrate that a therapeutic candidate's clinical and other benefits outweigh its safety risks;
- the FDA, EMA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our therapeutic candidates may not be sufficient to support the submission of a BLA or other submission or to obtain marketing approval in the United States or elsewhere;
- upon review of our clinical trial sites and data, the FDA or comparable foreign regulatory authorities may find our record keeping or the record keeping of our clinical trial sites to be inadequate or may identify other GCP deficiencies related to the trials;
- the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies may fail to meet the requirements of the FDA or comparable foreign regulatory authorities; or
- the medical standard of care or the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner that renders our clinical data insufficient for approval.

It is possible that none of the therapeutic candidates we may develop will obtain the marketing approvals necessary for us to sell the products either in the United States or any other country. Furthermore, approval by the FDA of a therapeutic product does not assure approval by regulatory authorities outside the United States or vice versa. Even if approval for a therapeutic product is obtained, such approval may be subject to limitations on the indicated uses or appropriate patient population that could result in a significantly reduced potential market size for the product.

If we fail to obtain the appropriate marketing approvals necessary for us to sell our therapeutic candidates, or if the approvals are more limited than those that we intend to seek, our business, financial condition and results of operations would be materially harmed.

We may attempt to secure approval from the FDA through the use of the accelerated approval pathway. If we are unable to obtain such approval, we may be required to conduct additional preclinical studies or clinical trials beyond those that we contemplate, which could increase the expense of obtaining, and delay the receipt of, necessary marketing approvals. Even if we receive accelerated approval from the FDA, if our confirmatory trials do not verify clinical benefit, or if we do not comply with rigorous post-marketing requirements, the FDA may seek to withdraw any accelerated approval we have obtained.

We may in the future seek accelerated approval for one or more of our therapeutic candidates. Under the accelerated approval program, the FDA may grant accelerated approval to a drug or biologic designed to treat a serious or life-threatening condition that provides meaningful therapeutic benefit over available therapies upon a determination that the drug or biologic has an effect on a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit. The FDA considers a clinical benefit to be a positive therapeutic effect that is clinically meaningful in the context of a given disease, such as irreversible morbidity or mortality. 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. An intermediate clinical endpoint is a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit.

The accelerated approval pathway may be used in cases in which the advantage of a new drug or biologic over available therapy may not be a direct therapeutic advantage, but is a clinically important improvement from a patient and public health perspective. If granted, accelerated approval is usually contingent on the sponsor's agreement to conduct, in a diligent manner, additional confirmatory studies to verity and describe the drug's predicted clinical benefit. If such post-approval studies fail to confirm the drug's clinical benefit or are not completed in a timely manner, the FDA may withdraw its approval of the drug on an expedited basis. In addition, the Food and Drug Omnibus Reform Act of 2022 provided FDA with stronger statutory authority to mitigate potential risks to patients

from continued marketing of ineffective drugs previously granted accelerated approval. Under these provisions, the FDA may require a sponsor of a product seeking accelerated approval to have a confirmatory trial underway prior to such approval being granted.

Prior to seeking accelerated approval for any of our therapeutics candidates, we intend to seek feedback from the FDA and will otherwise evaluate our ability to seek and receive accelerated approval. There can be no assurance that after our evaluation of the feedback and other factors we will decide to pursue or submit a BLA for accelerated approval or any other form of expedited development, review or approval. Furthermore, if we decide to submit an application for accelerated approval for our therapeutic candidates, there can be no assurance that such application will be accepted or that any expedited development, review or approval will be granted on a timely basis, or at all. The FDA or other comparable foreign regulatory authorities could also require us to conduct further studies prior to considering our application or granting approval of any type. A failure to obtain accelerated approval or any other form of expedited development, review or approval for our therapeutic candidates would result in a longer time period to commercialization of such therapeutic candidates, if any, could increase the cost of development of such candidate and could harm our competitive position in the marketplace.

We will be subject to stringent domestic and foreign therapeutic and drug regulation with respect to any potential products. Even if we receive marketing approval for any of our therapeutic candidates, we will still be subject to ongoing regulatory obligations and continued review, which may result in significant additional expense. If we fail to comply with United States and foreign regulatory requirements, regulatory authorities could limit or withdraw any marketing or commercialization approvals we may receive and subject us to other penalties. Any unfavorable regulatory action may materially and adversely affect our future financial condition and business operations.

Even if we receive marketing and commercialization approval for a therapeutic candidate, we will be subject to continuing post-marketing regulatory requirements. Our potential products, further development activities and manufacturing and distribution of a future product, once developed and determined, will be subject to extensive and rigorous regulation by numerous government agencies, including the FDA and comparable foreign agencies. To varying degrees, each of these agencies monitors and enforces our compliance with laws and regulations governing the development, testing, manufacturing, labeling, marketing, distribution, and the safety and effectiveness of our therapeutic candidates and, if approved, our future products. The process of obtaining marketing approval or clearance from the FDA and comparable foreign bodies for new products, or for enhancements, expansion of the indications or modifications to existing products, could:

- take a significant, indeterminate amount of time;
- require the expenditure of substantial resources;
- involve rigorous preclinical and clinical testing, and possibly post-market surveillance;
- require design changes of our potential products; or
- result in our never being granted the marketing approval we seek.

Any of these occurrences may cause our operations or potential for success to suffer, harm our competitive standing and result in further losses that adversely affect our financial condition.

The FDA, as well as its foreign regulatory counterparts, also have significant post-market authority, including the authority to require labeling changes based on new safety information and to require post-market studies or clinical trials to evaluate safety risks related to the use of a product or to require withdrawal of the product from the market. Additionally, the FDA regulates the promotional claims that may be made about prescription products, such as our products, if approved. In particular, a product may not be promoted for uses that are not approved by the FDA as reflected in the product's approved labeling. However, we may share truthful and not misleading information with healthcare providers and payors that is otherwise consistent with the product's FDA approved labeling.

We will have ongoing responsibilities under these and other FDA and international regulations, both before and after a product is approved and commercially released. Compliance with applicable regulatory requirements is subject to continual review and is monitored rigorously through periodic inspections by the FDA and foreign regulatory agencies. If we or our manufacturers or service providers fail to comply with applicable continuing regulatory requirements in the United States or foreign jurisdictions in which we seek to market our products, we or they may

be subject to, among other things, fines, warning letters, adverse regulatory inspection finding, holds on clinical trials, delay of approval or refusal by the FDA or applicable authorities to approve pending applications or supplements to approved applications, suspension or withdrawal of marketing approval, product recalls and seizures, administrative detention of products, refusal to permit the import or export of products, operating restrictions, exclusion of eligibility from government contracts, injunctions, civil penalties or criminal prosecution. Any adverse regulatory action, depending on its magnitude, may restrict us from effectively commercializing our potential products and harm our business. In addition, negative publicity and product liability claims resulting from any adverse regulatory action could have a material adverse effect on our business, financial condition, results of operations, and prospects.

The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses.

The FDA strictly regulates marketing, labeling, advertising and promotion of prescription drugs. These regulations include standards and restrictions for direct-to-consumer advertising, industry-sponsored scientific and educational activities, promotional activities involving the internet and off-label promotion. Any regulatory approval that the FDA grants is limited to those specific diseases and indications for which a product is deemed to be safe and effective by FDA. While physicians in the United States may choose, and are generally permitted, to prescribe drugs for uses that are not described in the product's labeling and for uses that differ from those tested in clinical trials and approved by the regulatory authorities, our ability to promote any products will be narrowly limited to those indications that are specifically approved by the FDA and comparable regulatory authorities.

If we are found to have promoted such off-label uses, we may become subject to significant liability. The U.S. federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we cannot successfully manage the promotion any therapeutic candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

The FDA, EMA and other comparable foreign regulatory authorities may not accept data from trials conducted outside of their respective jurisdictions. While we have previously formed partnerships in China designed to provide access to patient populations outside of the United States and in the future may conduct clinical trials in other foreign jurisdictions, there can be no assurance these data will be accepted by the FDA or EMA or other comparable foreign regulatory authorities as a basis for a product's marketing approval.

To augment our U.S.-centric clinical strategy, we have previously formed partnerships in China designed to provide access patient populations for clinical trials not readily available in the United States and to facilitate rapid patient enrollment with the goal of generating more robust early clinical data from patients in China. We may in the future pursue partnerships to conduct clinical trials outside of the United States. The acceptance of study data from clinical trials conducted outside the United States or another jurisdiction by the FDA or comparable foreign regulatory authority may be subject to certain conditions or may not be accepted at all. In cases where data from foreign clinical trials are intended to serve as the sole basis for regulatory 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 U.S. population and U.S. medical practice; (ii) the trials were performed by clinical investigators of recognized competence and pursuant to GCP regulations; and (iii) the data may be considered valid without the need for an on-site inspection by the FDA, or if the FDA considers such inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. In addition, even where the foreign study data are not intended to serve as the sole basis for approval, if the study was not otherwise subject to an IND, the FDA will not accept the data as support for an application for regulatory approval unless the study is well-designed and well-conducted in accordance with GCP requirements and the FDA is able to validate the data from the study through an onsite inspection if deemed necessary. Many foreign regulatory authorities have similar requirements for clinical data gathered outside of their respective jurisdictions. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. Many foreign regulatory bodies have similar approval requirements. In addition, any 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, including any trials conducted in China.

Disruptions at the FDA and other government agencies caused by funding or staffing shortages or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, prevent new or modified products from being developed, review, approved or commercialized in a timely manner or at all, which could negatively impact our business.

The ability of the FDA and foreign regulatory authorities to review and approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA's or foreign regulatory authorities' ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's or foreign regulatory authorities' ability to perform routine functions. Average review times at the FDA and foreign regulatory authorities have fluctuated in recent years as a result. In addition, government funding of other government agencies 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 biologics or modifications to approved and biologics to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, in recent years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities. Separately, in response to the COVID-19 pandemic, the FDA postponed most inspections at domestic and foreign manufacturing facilities from March 2020 until July 2021. If a prolonged government shutdown occurs, or if funding issues, staffing shortages, or renewed global health concerns otherwise hinder or prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Our partnerships in China subject us to risks and uncertainties relating to the laws and regulations of China and the changes in relations between the United States and China.

The government of China has pursued economic reform policies, including by encouraging foreign trade and investment. However, there is no assurance that the Chinese government will continue to pursue such policies, that such policies will be successfully implemented, that such policies will not be significantly altered, or that such policies will be beneficial to our partnerships in China. China's system of laws can be unpredictable, especially with respect to foreign investment and foreign trade. The U.S. government has called for substantial changes to foreign trade policy with China and has raised, and has proposed to further raise in the future, tariffs on several Chinese goods. China has retaliated with increased tariffs on U.S. goods. Moreover, China's legislature adopted a national security law to substantially change the way Hong Kong has been governed since the territory was handed over by the United Kingdom to China in 1997. This law increased the power of the central government in Beijing over Hong Kong, limited the civil liberties of residents of Hong Kong and could restrict the ability of businesses in Hong Kong to continue to conduct business as previously conducted. The U.S. State Department previously enacted sanctions related to China's governing of Hong Kong, and the United States has and may in the future impose the same tariffs and other trade restrictions on exports from Hong Kong that it places on goods from mainland China. Any further changes in United States trade policy could trigger retaliatory actions by affected countries, including China, resulting in trade wars. For example, the Uyghur Forced Labor Prevention Act, or UFLPA, imposes a rebuttable presumption that the importation of any goods produced or manufactured wholly or in part in the UFLPA-designated region, or produced by certain entities, is prohibited and that such goods are not permitted entry to the United States. This legislation may have an adverse effect on global supply chains which could adversely impact our business and results of operations. Additionally, the biopharmaceutical industry in particular in China is strictly regulated by the Chinese government. Changes to Chinese regulations affecting biopharmaceutical companies are also unpredictable. Any regulatory changes and changes in United States and China relations may have a material adverse effect on our partnerships in China which could materially harm our business and financial condition.

The successful commercialization of any product candidates for which we obtain approval will depend in part on the extent to which governmental authorities, private health insurers, and other third-party payors provide coverage and adequate reimbursement. Unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives could harm our business in the future.

Our ability to successfully commercialize any product candidates for which we obtain approval will depend in part on the extent to which coverage and reimbursement for these product candidates and related treatments will be available from government 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 provide reimbursement.

There is increasing pressure on biotechnology companies to reduce healthcare costs. In the United States, these pressures come from a variety of sources, such as managed care groups and institutional and government purchasers. Increased purchasing power of entities that negotiate on behalf of federal healthcare programs and private sector beneficiaries could increase pricing pressures in the future. Such pressures may also increase the risk of litigation or investigation by the government regarding pricing calculations. The biotechnology industry will likely face greater regulation and political and legal actions in the future.

Adverse pricing limitations may hinder our ability to recoup our investment in one or more future therapeutic candidates, even if our future therapeutic candidates obtain marketing approval. Adverse pricing limitations prior to approval will also adversely affect us by reducing our commercial potential. In addition, companion diagnostic tests require coverage and reimbursement separate and apart from the coverage and reimbursement for their companion pharmaceutical or biological products. Similar challenges to obtaining coverage and reimbursement, applicable to pharmaceutical or biological products, will apply to companion diagnostics.

A significant trend in the U.S. healthcare industry and elsewhere is cost containment. Third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. Third-party payors are increasingly challenging the prices charged, examining the medical necessity, and reviewing the cost-effectiveness of medical products and services and imposing controls to manage costs. Third-party payors may limit coverage to specific products on an approved list, also known as a formulary, which might not include all of the approved products for a particular indication.

A payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a product does not assure that other payors will also provide coverage and reimbursement for the product, and the level of coverage and reimbursement can differ significantly from payor to payor. Third-party reimbursement and coverage for our product candidates for which we receive approval may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development.

There may be significant delays in obtaining reimbursement for approved products, and coverage may be more limited than the purposes for which the product is approved by the FDA or regulatory authorities in other countries. Moreover, eligibility for reimbursement does not imply that any product will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim payments for new products, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Payment rates may vary according to the use of the product and the clinical setting in which it is used, may be based on payments allowed for lower cost products that are already reimbursed and may be incorporated into existing payments for other services. Net prices for products may be reduced by mandatory discounts or rebates required by third-party payors and by any future relaxation of laws that presently restrict imports of products 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, but also have their own methods and approval process apart from Medicare coverage and reimbursement determinations. Accordingly, one third-party payor's determination to provide coverage for a product does not assure that other payors will also provide coverage for the product. Our inability to promptly obtain coverage and adequate reimbursement from third-party payors for approved products could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize potential products and our overall financial condition. We cannot be sure that coverage and reimbursement will be available for any product that we commercialize in the future and, if reimbursement is available, what the level of reimbursement will be. Reimbursement may impact the demand for, or the price of, any

product for which we obtain marketing approval in the future. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any therapeutic candidate that we successfully develop.

Current and future healthcare reform legislation or regulation may increase the difficulty and cost for us to commercialize our product candidates, may adversely affect the prices we may obtain and may have a material and adverse effect on our business, financial condition, results of operations, and prospects.

In both the United States and certain foreign jurisdictions, there have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal, and state levels directed at containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future. In addition, third-party payors, whether domestic or foreign, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. The continuing efforts of the government, insurance companies, managed care organizations, and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls may adversely affect:

- the demand for our therapeutic candidates, if we obtain marketing approval;
- our ability to receive or set a price that we believe is fair for our products;
- our ability to generate revenue and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

For example, the Affordable Care Act, or ACA, was enacted in March 2010 and has significantly changed the way healthcare is financed by both governmental and private insurers in the United States. It also included the Biologics Price Competition and Innovation Act, or BPCIA, which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. Among the provisions of the ACA of importance to our potential drug candidates are the implementation of a new methodology for calculating rebates owed by manufacturers under the Medicaid Drug Rebate Program for drugs that are inhaled, infused, instilled, implanted or injected; an increase of the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program; expanding manufacturer Medicaid rebate liability to include utilization under Medicaid managed care organizations; and establishing annual fees on manufacturers of certain branded prescription drugs.

Since its enactment, certain provisions of the ACA have been subject to judicial, executive, and legislative challenges. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Thus, the ACA will remain in effect in its current form.

As another example, the American Rescue Plan Act of 2021 included a provision that eliminated the statutory cap on manufacturer Medicaid rebates. Beginning in January 2024, Medicaid rebates are no longer capped at 100 percent of the drug's average manufacturer price.

Moreover, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products.

Most significantly, in August 2022, the Inflation Reduction Act of 2022, or IRA, was signed into law. This statute marks the most significant action by Congress with respect to the pharmaceutical industry since adoption of the ACA in 2010. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare, with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023); redesigns the Medicare Part D benefit (beginning in 2024); and replaces the Part D coverage gap discount program with a new manufacturer discount program (beginning in 2025). CMS has published the negotiated prices for the initial ten drugs, which will first be effective in 2026, and has published the list of the subsequent 15 drugs that will be subject to negotiation.

The IRA permits the Secretary of the 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, although the Medicare drug price negotiation program is currently subject to legal challenges. While the impact of the IRA on the pharmaceutical industry cannot yet be fully determined, it is likely to be significant.

At the state level, legislatures have increasingly passed legislation and implemented 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, drug price reporting and other transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Some states have enacted legislation creating so-called prescription drug affordability boards, which ultimately may attempt to impose price limits on certain drugs in these states.

We expect that the ACA, the IRA, as well as other healthcare reform measures that may be adopted in the future may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, lower reimbursement, and new payment methodologies. This could lower the price that we receive for any approved product. Any denial in coverage or reduction in reimbursement from Medicare or other government-funded programs may result in a similar denial or reduction in payments from private payors, which may prevent us from being able to generate sufficient revenue, attain profitability, or commercialize our therapeutic candidates, if approved.

In the EU, similar political, economic and regulatory developments may affect our ability to profitably commercialize our current or any future products. In addition to continuing pressure on prices and cost containment measures, legislative developments at the EU or member state level may result in significant additional requirements or obstacles that may increase our operating costs. For instance, the European Commission launched its Pharmaceutical Strategy for Europe initiative in November 2020. The European Commission published its proposals for revision related to medicinal products (potentially reducing the duration of regulatory data protection and revising the eligibility for expedited pathways, among other potential revisions) in April 2023. There may be substantial revisions before the European Parliament and European Council adopts any of the proposals which is not anticipated before early 2026. The revisions may however have a significant impact on the pharmaceutical industry and our business in the long term. In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. Our future products, if any, might not be considered medically reasonable and necessary for a specific indication or cost-effective by third-party payors, an adequate level of reimbursement might not be available for such products and third-party payors' reimbursement policies might adversely affect our ability to sell any future products profitably.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, our therapeutic candidates may lose any marketing approval that may have been obtained and we may not achieve or sustain profitability, which would adversely affect our business.

If we or our partners, manufacturers or service providers fail to comply with healthcare laws and regulations, we or they could be subject to enforcement actions, which could affect our ability to develop, market and sell our products and may harm our reputation.

Healthcare providers, physicians and third-party payors play a primary role in the recommendation and prescription of any therapeutic candidates for which we may obtain marketing approval. Our current and future arrangements with healthcare providers, third-party payors and customers 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 our therapeutic candidates for which we obtain marketing approval. In addition, we may be subject to patient data privacy and security regulation by both the U.S. federal government and the states in which we conduct our business. Restrictions under applicable federal and state healthcare laws and regulations, include the following:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind to induce or reward either the referral of an individual for, or the purchase, or order or recommendation of, any good or service, for which payment may be made under federal and state healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the federal civil and criminal false claims laws, including the U.S. federal False Claims Act, which can be enforced through civil whistleblower or qui tam actions, and the civil monetary penalties laws, which prohibit individuals or entities from knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the U.S. federal False Claims Act;
- the federal Health Insurance Portability and Accountability Act of 1996 and its accompanying regulations, or HIPAA, which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services; similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the U.S. federal legislation commonly referred to as the Physician Payments Sunshine Act, enacted as part of the ACA, and its implementing regulations, which requires certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program to report annually to the United States Department of Health and Human Services, or HHS, information related to certain payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors), certain advanced non-physician healthcare practitioners and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members; and
- analogous state laws and regulations, such as state anti-kickback and false claims laws that may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private 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 in addition to requiring drug and therapeutic biologics manufacturers to report information related to payments to physicians and other healthcare providers or marketing expenditures and pricing information; and state and local laws that require the registration of pharmaceutical sales representatives.

Ensuring that our future business arrangements with third parties comply with applicable healthcare laws and regulations could involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any such requirements, we may be subject to significant civil, criminal and administrative penalties, including monetary damages, fines, disgorgements, imprisonment, loss of eligibility to obtain approvals from the FDA, exclusion from participation in government contracting, healthcare reimbursement or other government programs, including Medicare and Medicaid, reputational harm, diminished profits and future earnings, additional reporting requirements if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with any of these laws, and the curtailment or restructuring of our operations, any of which could adversely our financial results. Although effective compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, these risks cannot be entirely eliminated. Any action against us for an alleged or suspected violation could cause us to incur significant legal expenses and could divert our management's attention from the operation of our business, even if our defense is successful. In addition, achieving and sustaining compliance with applicable laws and regulations may be costly to us in terms of money, time and resources.

We received orphan drug status for ozekibart (INBRX-109) for the treatment of patients with metastatic or unresectable chondrosarcoma. We may seek orphan drug status for additional therapeutic candidates, but even if it is granted, we may be unable to maintain any benefits associated with orphan drug status, including the potential for market exclusivity.

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition, which is defined as one occurring in a patient population of fewer than 200,000 in the United States, or for which there is no reasonable expectation that the cost of developing and making available in the United States a drug or biologic for a disease or condition will be recovered from sales in the United States for that drug or biologic. In the U.S., orphan designation entitles a party to financial incentives such as opportunities for grant funding for clinical trial costs, tax advantages and user-fee waivers. If a therapeutic candidate that has orphan drug designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications, including a full BLA, to market the same drug or biologic for the same disease or condition for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity.

We received orphan drug status for ozekibart (INBRX-109) for the treatment of patients with metastatic or unresectable chondrosarcoma. We may seek orphan drug status for additional therapeutic candidates, but the FDA may not grant any such request. Even with orphan drug status, exclusive marketing rights in the United States may be limited if we seek FDA marketing approval for an indication broader than the therapeutic candidate's orphan designated disease or condition. Additionally, any therapeutic candidate that initially receives orphan drug status designation, may lose such designation if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition. Further, even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs with different active ingredients may be approved for the same disease or condition. Even after an orphan drug is approved, the FDA can subsequently approve the same drug for the same disease or condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care, or the manufacturer of the product with orphan exclusivity is unable to maintain sufficient product quantity. Orphan drug designation neither shortens the development or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process.

We received Fast Track designation for ozekibart (INBRX-109) for the treatment of patients with metastatic or unresectable chondrosarcoma. We may seek Fast Track designation for other of our therapeutic candidates. Even if received, Fast Track designation may not actually lead to a faster review process.

We received Fast Track designation for ozekibart (INBRX-109) for the treatment of patients with metastatic or unresectable chondrosarcoma. Depending on the data from our preclinical and clinical studies, we may decide to seek such designation for some or all of our other therapeutic candidates. The Fast Track program is intended to expedite or facilitate the process for reviewing candidates that meet certain criteria. Specifically, drugs and biologics are eligible for Fast Track designation if they are intended, alone or in combination with one or more drugs or biologics, to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Fast Track designation applies to the combination of the candidate and the specific indication for which it is being studied. The sponsor of a Fast Track therapeutic candidate has opportunities for more frequent interactions with the applicable FDA review team during product development and under Fast Track designation, the FDA may initiate a rolling review of sections of a BLA before the application is complete, if the sponsor provides a schedule for the submission of the sections of the BLA, the FDA agrees to accept sections of the BLA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the application.. However, the FDA's time period goal for reviewing an application does not begin until the last section of the BLA is submitted.

The FDA has broad discretion whether or not to grant Fast Track designation. Even if we believe a particular therapeutic candidate is eligible for this designation, we cannot assure you that the FDA would decide to grant it. Even if we do receive Fast Track designation for any of our other therapeutic candidates, such therapeutic candidates may not experience a faster development process, review or approval compared to conventional FDA procedures.

The FDA may also withdraw Fast Track Designation if it believes that the designation is no longer supported by data from our clinical development program. Furthermore, such a designation does not increase the likelihood that ozekibart (INBRX-109) or any other therapeutic candidate that may be granted Fast Track designation will receive marketing approval in the U.S. Many therapeutic candidates that have received Fast Track designation have ultimately failed to obtain approval.

Our therapeutic candidates for which we intend to seek approval may face competition sooner than anticipated.

Even if we are successful in achieving marketing approval to commercialize a therapeutic candidate ahead of our competitors, our future therapeutic candidates may face direct competition from biosimilar products. In the United States, our therapeutic candidates are regulated by the FDA as biological products, and we intend to seek approval for these therapeutic candidates pursuant to the BLA pathway. The BPCIA created an abbreviated pathway for the FDA approval of biosimilar biological products based on a previously licensed innovator, or reference, biological product. Under the BPCIA, an application for a biosimilar biological product cannot be approved by the FDA until 12 years after the original reference biological product was approved under a BLA.

We believe that any of our therapeutic candidates approved as a biological product under a BLA should qualify for the 12-year period of exclusivity available to reference biological products. However, there is a risk that this exclusivity could be shortened due to Congressional action or otherwise, or that the FDA will not consider our therapeutic candidates to be reference biological products pursuant to its interpretation of the exclusivity provisions of the BPCIA, potentially creating the opportunity for follow-on biosimilar competition sooner than anticipated. Moreover, the extent to which a biosimilar product, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing. In addition, a competitor could decide to forego the abbreviated approval pathway available for biosimilar products and to submit a full BLA for product licensure after completing its own preclinical studies and clinical trials. In such a situation, any exclusivity to which we may be eligible under the BPCIA would not prevent the competitor from marketing its biological product as soon as it is approved.

In the EU, the European Commission has granted marketing authorizations for many biosimilar products pursuant to a set of general and product class-specific guidelines for biosimilar approvals issued over the past few years. In addition, companies may be developing biosimilar products in other countries that could compete with our products, if approved.

If competitors are able to obtain marketing approval for biosimilars referencing our therapeutic candidates, if approved, our future products may become subject to competition from such biosimilars, whether or not they are designated as interchangeable, with the attendant competitive pressure and potential adverse consequences. Such competitive products may be able to immediately compete with us in each indication for which our therapeutic candidates may have received approval.

Actual or perceived failures to comply with applicable privacy, data protection and information security laws, regulations and standards and other requirements could adversely affect our business, results of operations, and financial performance.

The global data protection landscape is rapidly evolving, and we are or may become subject to numerous state, federal and foreign laws, requirements and regulations governing the collection, use, disclosure, retention, and security of personal information, such as information that we may collect in connection with clinical trials in the United States and abroad. We are subject to numerous U.S. federal and state laws and non-U.S. regulations, including in Europe and China, governing the protection of personal and confidential information of our clinical subjects, clinical investigators, employees and vendors/business contacts, including in relation to health-related information and other personal information. Implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future, and we cannot yet determine the impact future laws, regulations, standards, or perception of their requirements may have on our business. This evolution may create uncertainty in our business, affect our ability to operate in certain jurisdictions or to collect, store, transfer use and share personal information, necessitate the acceptance of more onerous obligations in our contracts, result in liability or impose additional costs on us. The cost of compliance with these laws, regulations and standards is high and is likely to

increase in the future. Any failure or perceived failure by us to comply with federal, state or foreign laws or regulations, our internal policies and procedures or our contracts governing our processing of personal information could result in negative publicity, government investigations and enforcement actions, claims by third parties and damage to our reputation, any of which could have a material adverse effect on our business, results of operation, and financial condition.

In the United States, numerous federal and state laws and regulations, including federal health information privacy laws, state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), that govern the collection, use, disclosure and protection of health-related and other personal information could apply to our operations. HIPAA imposes, among other things, certain standards relating to the privacy, security, transmission and breach reporting of individually identifiable health information. Most healthcare providers, including research institutions from which we obtain patient health information, are subject to privacy and security regulations promulgated under HIPAA. While we do not believe that we are currently acting as a covered entity or business associate under HIPAA and thus are not directly regulated under HIPAA, any person may be prosecuted under HIPAA's criminal provisions either directly or under aiding-and-abetting or conspiracy principles. Consequently, depending on the facts and circumstances, we could face substantial criminal penalties if we knowingly receive individually identifiable health information from a HIPAA-covered healthcare provider or research institution that has not satisfied HIPAA's requirements for disclosure of individually identifiable health information.

Certain states have also adopted comparable privacy and security laws and regulations, which govern the privacy, processing and protection of health-related and other personal information. Such laws and regulations will be subject to interpretation by various courts and other governmental authorities, thus creating potentially complex compliance issues for us and our future customers and strategic partners. For example, the California Consumer Privacy Act, as amended by the California Privacy Rights Act, or collectively, the CCPA, requires covered businesses that process the personal information of California residents to, among other things: (i) provide certain disclosures to California residents regarding the business's collection, use, and disclosure of their personal information; (ii) receive and respond to requests from California residents to access, delete, and correct their personal information, or to opt out of certain disclosures of their personal information; and (iii) enter into specific contractual provisions with service providers that process California resident personal information on the business's behalf. Similar laws have been passed in other states, and are continuing to be proposed at the state and federal level, reflecting a trend toward more stringent privacy legislation in the United States. The enactment of such laws could have potentially conflicting requirements that would make compliance challenging.

In Europe and the UK, we are subject to the GDPR, which comprehensively regulates our use of personal data, including cross-border transfers of personal data out of the EEA and the UK. In addition, some of the personal data we process in respect of clinical trial participants is special category or sensitive personal data under the GDPR, and subject to additional compliance obligations and to local law derogations. We may be subject to diverging requirements under EU member state laws and UK law, such as whether consent can be used as the legal basis for processing and the roles, responsibilities and liabilities as between sites and sponsors. As these laws develop, we may need to make operational changes to adapt to these diverging rules, which could increase our costs and adversely affect our business.

In relation to such cross border transfers of personal data, we expect the existing legal complexity and uncertainty regarding international personal data transfers to continue. In particular, we expect the European Commission approval of the current EU-US Data Privacy Framework for data transfers to certified entities in the United States to be challenged and international transfers to the United States and to other jurisdictions more generally to continue to be subject to enhanced scrutiny by regulators. As the regulatory guidance and enforcement landscape in relation to data transfers continue to develop, we could suffer additional costs, complaints and/or regulatory investigations or fines; we may have to stop using certain tools and vendors and make other operational changes; we may have to implement alternative data transfer mechanisms under the GDPR and/ or take additional compliance and operational measures; and/or it could otherwise affect the manner in which we provide our services, and could adversely affect our business, operations and financial condition.

Failure to comply with the GDPR could result in penalties for noncompliance. Since we are subject to the supervision of relevant data protection authorities under multiple legal regimes (including under both the EU GDPR and the UK GDPR), we could be fined under those regimes independently in respect of the same breach. In addition to fines, a breach of the GDPR may result in regulatory investigations, reputational damage, orders to cease/change our data processing activities, enforcement notices, assessment notices (for a compulsory audit) and/or civil claims (including class actions).

Where we rely on third parties to carry out a number of services for us, including processing personal data on our behalf, we are required under GDPR and the U.S. state privacy laws to enter into contractual arrangements to help ensure that these third parties only process such data according to our instructions and have sufficient security measures in place. Any security breach or non-compliance with our contractual terms or breach of applicable law by such third parties could result in enforcement actions, litigation, fines and penalties or adverse publicity and could cause our customers to lose trust in us, which could have an adverse impact on our reputation and business.

Our partnerships in China may expose us to stringent Chinese data security and personal information protection laws and regulations. The Data Security Law of the People's Republic of China, or the PRC Data Security Law, took effect on September 1, 2021 and applies extraterritorially, and to a broad range of activities that involve "data" (not only personal or sensitive data). The PRC Data Security Law requires data processing, which includes the collection, storage, use, processing, transmission, provision and publication of data, to be conducted in a legitimate and proper manner. Moreover, the PRC Data Security Law provides a national security review procedure for those data processing activities which affect or may affect national security and requires 'important data' to be stored locally in China unless one complies with certain data transfer restrictions, such as passing a security assessment organized by the relevant authorities. In addition, the PRC Data Security Law also provides that any organization or individual within the territory of the PRC shall not provide any foreign judicial body and law enforcement body with any data stored in the territory of the PRC without the approval of the competent PRC governmental authorities. Also in China, the Personal Information Protection Law, or PIPL, which took effect on November 1, 2021, introduced stringent protection requirements for processing personal information. Notably, a data export mechanism, such as a security assessment, entering into a standard contract with the overseas recipient and obtaining a personal information protection certification, must be relied on in order for a personal information processor to export personal information out of China, unless an exemption applies. In addition to the PRC Data Security Law and PIPL, the PRC government authorities promulgated several regulations to provide further implementation guidance in accordance with the laws mentioned above. For example, the Regulations on Network Data Security Management, or the Regulations, which recently took effect on January 1, 2025 in China, have extraterritorial effect and apply broadly to any network data processing activities (not only personal data processing activities). The Regulations reiterate and expand on the existing obligations on data processors under the PRC Cybersecurity Law, PRC Data Security Law and the PIPL and introduce new data security obligations, such as a requirement to report any risks arising from network products and services that may endanger national security or public interest to the relevant authorities within 24 hours. We cannot predict what impact the new laws and regulations or the increased costs of compliance, if any, will have on our operations in China. We may also be required to make further significant adjustments to our business practices to comply with data security and personal information protection laws in China.

We are subject to U.S. and certain foreign export and import controls, sanctions, embargoes, anti-corruption laws, and anti-money laundering laws and regulations. Compliance with these legal standards could impair our ability to compete in domestic and international markets. We can face criminal liability and other serious consequences for violations, which can harm our business.

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls, the U.S. Foreign Corrupt Practices Act of 1977, as amended, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, and other state and national anti-bribery and anti-money laundering laws in the countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors, and other collaborators from authorizing, promising, offering, or providing, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. We may engage third

parties to sell our products sell our products outside the United States, to conduct clinical trials, and/or to obtain necessary permits, licenses, patent registrations, and other marketing approvals. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors, and other collaborators, even if we do not explicitly authorize or have actual knowledge of such activities. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences.

Furthermore, U.S. export control laws and economic sanctions prohibit the provision of certain products and services to countries, governments, and persons targeted by U.S. sanctions. U.S. sanctions that have been or may be imposed as a result of military conflicts in other countries may impact our ability to continue activities at future clinical trial sites within regions covered by such sanctions. If we fail to comply with export and import regulations and such economic sanctions, penalties could be imposed, including fines and/or denial of certain export privileges. These export and import controls and economic sanctions could also adversely affect our supply chain.

If we do not comply with laws regulating the protection of the environment and health and human safety, our business could be adversely affected.

We maintain quantities of various flammable and toxic chemicals in our facilities in La Jolla, California required for our research and development activities. We are subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous materials. We believe our procedures for storing, handling and disposing these hazardous materials in our La Jolla facilities comply with the relevant guidelines of La Jolla, the state of California and the Occupational Safety and Health Administration of the U.S. Department of Labor. Although we believe that our safety procedures for handling and disposing of these materials comply with the standards mandated by applicable regulations, the risk of accidental contamination or injury from these materials cannot be eliminated. If an accident occurs, we could be held liable for resulting damages, which could be substantial. We are also subject to numerous environmental, health and workplace safety laws and regulations, including those governing laboratory procedures, exposure to blood-borne pathogens and the handling of animals and biohazardous materials. Any insurance coverage we have may not be sufficient to cover these liabilities. Additional federal, state and local laws and regulations affecting our operations may be adopted in the future. We may incur substantial costs to comply with, and substantial fines or penalties if we violate, any of these laws or regulations which would adversely affect our business.

Our future growth may depend, in part, on our ability to operate in foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties.

Our future growth may depend, in part, on our ability to develop and commercialize our therapeutic candidates, if approved, in foreign markets for which we may rely on collaboration with third parties. We are not permitted to market or promote any of our therapeutic candidates before we receive marketing approval from the applicable regulatory authority in that foreign market, and we may never receive such marketing approval for any of our therapeutic candidates. To obtain separate marketing approval in many other countries we must comply with numerous and varying regulatory requirements of such countries regarding safety and efficacy and governing, among other things, clinical trials and commercial sales, pricing and distribution of our therapeutic candidates, and we cannot predict success in these jurisdictions. If we obtain approval of our therapeutic candidates and ultimately commercialize our therapeutic candidates in foreign markets, we would be subject to the risks and uncertainties, including the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements and the reduced protection of intellectual property rights in some foreign countries. We may need to rely on third parties to market, distribute and sell our products in foreign markets.

Risks Related to Ownership of Our Common Stock

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

Our common stock was listed on the Nasdaq Global Market on May 30, 2024. Although trading in our common stock has developed, we cannot assure you that an active trading market will continue to develop or be sustained or

that any trading market will be liquid. The lack of an active market may impair your ability to sell your shares at the time you wish to sell them or at a price that you consider reasonable. The lack of an active market may also reduce the fair market value of your shares. Furthermore, an inactive market may also impair our ability to raise capital by selling shares of our common stock and may impair our ability to enter into strategic collaborations or acquire companies, technologies or other assets by using our shares of common stock as consideration.

We expect that our stock price may fluctuate significantly.

The trading price of shares of our common stock may be highly volatile and could be subject to wide fluctuations in response to many risk factors listed in this section, and others beyond our control, including:

- results of our clinical trials and preclinical studies or those of our competitors;
- the success of competitive products or technologies;
- regulatory or legal developments in the United States and other countries;
- geopolitical events, such as global conflicts or hostilities;
- the level of expenses related to our therapeutic candidates or development programs;
- changes in the structure of healthcare payment systems; actual or anticipated fluctuations in our financial condition and operating results;
- announcements by us, our partners or our competitors of new therapeutics or therapeutic candidates, significant contracts, strategic partnerships, joint ventures, collaborations, commercial relationships or capital commitments;
- failure to meet or exceed financial estimates and projections of the investment community or that we provide to the public;
- issuance of new or updated research or reports by securities analysts or recommendations for our stock;
- disputes or other developments related to proprietary rights, including patents, litigation matters, and our ability to obtain patent protection for our technologies;
- commencement of, or our involvement in, litigation;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- manufacturing disputes or delays;
- any future sales of our common stock, including upon the exercise of the warrants to purchase our common stock, or other securities;
- any change to the composition of the board of directors or key personnel;
- expiration of contractual lock-up agreements with our executive officers, directors and security holders;
- general economic conditions and slow or negative growth of our markets;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- announcement or expectation of additional debt or equity financing efforts; and
- circumstances and market conditions relating to pandemics and natural disasters.

These and other market and industry factors may cause the market price and demand for our common stock to fluctuate substantially, regardless of our actual operating performance. In addition, the stock market in general, and life science companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. In the past, when the market price of a stock has been volatile, holders of that stock have on occasion instituted securities class action litigation against the company that issued the stock. If any of our stockholders were to bring a lawsuit against us, the defense and disposition of the lawsuit could be costly and divert the time and attention of our management and harm our operating results.

Our executive officers, directors and holders of more than 5% of our capital stock own a significant percentage of our stock and are able to exercise significant control over matters subject to stockholder approval.

As of December 31, 2024, our executive officers, directors and holders of more than 5% of our capital stock beneficially owned approximately 62% of our shares of common stock outstanding. Accordingly, this group of stockholders will continue to have significant control over our operations. This concentration of ownership could have the effect of delaying or preventing a change in our control or otherwise discouraging a potential acquirer from attempting to obtain control of us, which in turn could have a material adverse effect on our stock price and may prevent attempts by our stockholders to replace or remove the board of directors or management.

Future sales of our common stock in the public market could cause our stock price to fall.

Our stock price could decline as a result of sales of a large number of shares of our common stock or the perception that these sales could occur. These sales, or the possibility that these sales may occur, also might make it more difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate.

As of December 31, 2024, we had 14,475,904 shares of common stock outstanding. All of our shares of common stock issued in the Distribution are freely tradable without restriction or further registration under the Securities Act unless the shares are owned by our "affiliates" as that term is defined in the rules under the Securities Act or are subject to other contractual restrictions. Shares held by "affiliates" may be sold in the public market only if registered or if they qualify for an exemption from registration or in compliance with Rule 144 under the Securities Act, or Rule 144. Shares held by the Former Parent may be sold, subject to compliance with applicable securities laws.

We have reserved approximately 4,000,000 shares for future grants under our Omnibus Incentive Plan. Any common stock that we issue, including under our Omnibus Incentive Plan or other equity incentive plans that we may adopt in the future, would dilute the percentage ownership held by our existing stockholders.

As of December 31, 2024 issued and outstanding warrants to purchase shares of our common stock consisted of warrants to purchase up to 991,849 shares of common stock. To the extent any of these warrants are exercised, additional shares of our common stock will be issued, which will result in dilution to the holders of our shares of common stock and an increase in the number of shares eligible for resale in the public market, subject to compliance with applicable securities laws. The holders of warrants have certain registration rights with respect to our common stock. In addition, in January 2025, in connection with the 2025 Loan Agreement, we issued to the lenders warrants to purchase 140,741 shares of our common stock.

We cannot predict what effect, if any, sales of our shares in the public market or the availability of shares for sale will have on the market price of our common stock. However, future sales of substantial amounts of our common stock in the public market, including shares issued in the Distribution, shares retained by the Former Parent, shares issued under our Omnibus Incentive Plan or shares issued upon exercise of the warrants, or the perception that such sales may occur, could adversely affect the market price of our common stock.

Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our technologies or therapeutic candidates.

We may seek additional capital through a combination of public and private equity offerings, debt financings, strategic partnerships and alliances, and licensing arrangements. We, and indirectly, our stockholders, will bear the cost of issuing and servicing such securities. Because our decision to issue debt or equity securities in any future offering will depend on market conditions and other factors beyond our control, we cannot predict or estimate the amount, timing, or nature of any future offerings. To the extent that we raise additional capital through the sale of equity or debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a stockholder. The incurrence of indebtedness would result in increased fixed payment obligations and could involve restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell, or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. Additionally, any future collaborations we enter into with third parties may provide capital in the near term but limit our potential cash flow and revenue in the future. If we raise additional funds through strategic partnerships and alliances and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or therapeutic candidates, or grant licenses on terms unfavorable to us.

If securities or industry analysts do not publish research reports about our business, or if they issue an adverse opinion about our business, our stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that industry or securities analysts publish about us or our business. If one or more of the analysts who cover us issues an adverse opinion about our company, our stock price could decline. If one or more of these analysts ceases coverage of us or fails to

regularly publish reports on us, we could lose visibility in the public markets, which could cause our stock price or trading volume to decline.

The Nasdaq Stock Market may delist our securities from its exchange, which could limit investors' ability to make transactions in our securities and subject us to additional trading restrictions.

Our common stock began trading on the Nasdaq Global Market on May 30, 2024. We cannot assure you that, in the future, our securities will meet the continued listing requirements to be listed on the Nasdaq Global Market. If Nasdaq delists our common stock, we could face significant material adverse consequences, including:

- a limited availability of market quotations for our securities;
- a determination that our common stock is a "penny stock" which will require brokers trading in our common stock to adhere to more stringent rules and possibly resulting in a reduced level of trading activity in the secondary trading market for our common stock;
- a limited amount of news and analyst coverage for our company; and
- a decreased ability to issue additional securities or obtain additional financing in the future.

We do not intend to pay dividends on our common stock so any returns will be limited to the value of our stock.

We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Future debt financing agreements may limit or require us to have the lender's permission before declaring dividends on our common stock. Any return to stockholders will therefore be limited to the appreciation of their stock.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial statements and other public reporting, which would harm our business and the trading price of our common stock.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. Pursuant to Section 404 of the Sarbanes-Oxley Act, or Section 404, our management will be required to report upon the effectiveness of our internal control over financial reporting.

The rules governing the standards that must be met for management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation. To comply with the requirements of being a reporting company under the Exchange Act, we will need to implement additional financial and management controls, reporting systems and procedures.

We cannot assure you that there will not be material weaknesses or significant deficiencies identified in our internal control over financial reporting in the future. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations or cash flows. In the future, if we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by Nasdaq, the SEC, or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

If we become an "accelerated filer," as defined in the Exchange Act, our independent registered public accounting firm will be required to attest to the effectiveness of our internal controls over financial reporting pursuant to Section 404. An independent assessment of the effectiveness of our internal controls could detect problems that our management's assessment might not. Undetected material weaknesses in our internal controls could lead to financial statement restatements and require us to incur the expense of remediation.

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

As a public company, we incur significant legal, accounting and other expenses that we would not incur as a private company. We are subject to the reporting requirements of the Exchange Act, which require, among other things, that we file with the SEC annual, quarterly and current reports with respect to our business and financial condition. In addition, the Sarbanes-Oxley Act as well as rules subsequently adopted by the SEC and Nasdaq to implement provisions of the Sarbanes-Oxley Act, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Further, in July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, was enacted. There are significant corporate governance and executive compensation-related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas such as "say on pay" and proxy access. Stockholder activism, the political environment and the level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate. If the rules and regulations applicable to public companies divert the attention of our management and personnel from other business concerns, they could have a material adverse effect on our business, financial condition and results of operations. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

Anti-takeover provisions contained in our certificate of incorporation and bylaws, as well as provisions of Delaware law, could impair a takeover attempt.

Our certificate of incorporation, bylaws and Delaware law contains provisions that could have the effect of rendering more difficult, delaying or preventing an acquisition deemed undesirable by our board of directors. Our corporate governance documents include provisions:

- authorizing our board of directors to issue up to 15,000,000 shares of preferred stock without stockholder approval upon the terms and conditions and with the rights, privileges and preferences as our board of directors may determine;
- specifying that special meetings of our stockholders can be called only by our board of directors, the chairperson of our board of directors or our Chief Executive Officer and that our stockholders may not act by written consent;
- establishing an advance notice procedure for stockholder proposals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to our board of directors;
- providing that our board of directors may create new directorships and 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;
- establishing 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;
- providing that our board of directors may amend our bylaws without stockholder approval; and
- requiring a super-majority of votes to amend certain of the above-mentioned provisions.

These provisions, alone or together, could delay or prevent hostile takeovers and changes in control or changes in our management.

As a Delaware corporation, we are also subject to provisions of Delaware law, including Section 203 of the DGCL, which prevents some stockholders holding more than 15% of our outstanding common stock from engaging in certain business combinations without approval of the holders of substantially all of our outstanding common stock.

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

Our certificate of incorporation designates the Court of Chancery of the State of Delaware, or the Chancery Court, or the federal district court for the District of Delaware, or the District Court of Delaware, or the other federal district courts of the United States as the exclusive forum for certain types of actions and proceedings that

may be initiated by 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 certificate of incorporation requires, unless we otherwise consent, that the Chancery Court will, to the fullest extent permitted by law, be the sole and exclusive forum for the following types of actions or proceedings under Delaware statutory or common law (subject to the Chancery Court having personal jurisdiction over the indispensable parties named as defendants): (i) any derivative action or proceeding brought on our behalf, (ii) any action or proceeding asserting a claim of breach of a fiduciary duty owed by any of our current or former directors, officers and employees to us or our stockholders, (iii) any action or proceeding asserting a claim against us or any of our current or former directors, officers or employees of the Company, arising out of or pursuant to any provision of the DGCL, our certificate of incorporation or our bylaws, (iv) any action or proceeding to interpret, apply, enforce or determine the validity of our certificate of incorporation or our bylaws, (v) any action or proceeding as to which the DGCL confers jurisdiction to the Chancery Court, or (vi) any action or proceeding asserting a claim against us, or our directors, officers or employees, governed by the internal affairs doctrine. If the Chancery Court does not have jurisdiction for these actions or proceedings, then the actions or proceedings must be brought in a state court located in the State of Delaware. If these state courts also do not have jurisdiction, these actions or proceedings must be brought in the federal district court for the District of Delaware. These limitations in our certificate of incorporation will not apply to actions brought to enforce a duty or liability created by the Securities Act, the Exchange Act or to any claim for which the federal courts have exclusive jurisdiction. However, our certificate of incorporation also provides that, unless we otherwise consent in writing, the federal district courts of the United States shall, to the fullest extent permitted by law, be the sole and exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act. In addition, any person holding, owning or otherwise acquiring any interest in any of our securities shall be deemed to have notice of and to have consented to these provisions of our certificate of incorporation. These choice of forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees and result in increased costs for investors to bring a claim. By agreeing to this provision, however, stockholders will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder. Furthermore, the enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that a court could find these types of provisions to be inapplicable or unenforceable. If a court were to find the choice of forum provisions in our 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.

We may be subject to securities litigation that materially diverts the attention of our management or pursuant to which we incur substantial costs.

The market price of our common stock may be volatile and, in the past, companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. Securities litigation against us could result in substantial costs and materially divert our management's attention from other business concerns, which could seriously harm our business.

We are an "emerging growth company," and we cannot be certain if the reduced reporting requirements applicable to "emerging growth companies" will make our Common Sock less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act. For as long as we continue to be an "emerging growth company," we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies," including not being required to comply with the auditor attestation requirements of Section 404, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. As an "emerging growth company," we are required to report only two years of financial results in certain Securities Act registration statements. We may take advantage of these exemptions until we are no longer an "emerging growth company." We will remain an "emerging growth company" for up to five years after the completion of the Distribution, although we will lose that status sooner if our revenues exceed $1.235 billion, if we issue more than $1 billion in non-convertible debt in a three-year period, or if the market value of our common stock

that are held by non-affiliates exceeds $700 million as of June 30 of a fiscal year. We cannot predict if investors will find our common stock less attractive because we may 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 the price of our common stock may be more volatile than that of an otherwise comparable company that does not avail itself of the same or similar exemptions.

We are a smaller reporting company, and the reduced reporting requirements applicable to smaller reporting companies may make our common stock less attractive to investors.

We are a "smaller reporting company" as defined in Rule 12b-2 under the Exchange Act. For as long as we continue to be a smaller reporting company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not smaller reporting companies, including reduced financial statement and other financial information disclosure, and reduced disclosure obligations regarding executive compensation in our annual and periodic reports and proxy statements. We will remain a smaller reporting company as long as either (i) the market value of our common stock held by non-affiliates is less than $250 million or (ii) our annual revenue is less than $100 million during the most recently completed fiscal year and the market value of our common stock held by non-affiliates is less than $700 million. Our public float is measured as of the last business day of our most recently completed second fiscal quarter, and annual revenues are as of the most recently completed fiscal year for which audited financial statements are available. We cannot predict if investors will find our common stock less attractive because we may 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 share price may be more volatile than that of an otherwise comparable company that does not avail itself of the same or similar exemptions.

Item 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity.

Cybersecurity

We recognize the critical importance of maintaining the trust and confidence of our patients, business partners and employees toward our business and are committed to protecting the confidentiality, integrity and availability of our business operations and systems. Our board of directors is actively involved in oversight of our risk management activities, and cybersecurity represents an important element of our overall approach to risk management. Our cybersecurity policies, standards, processes and practices are based on recognized frameworks established by the National Institute of Standards and Technology, or NIST, the International Organization for Standardization and other applicable industry standards. This does not imply that we meet any particular technical standards, specifications, or requirements, only that we use the NIST framework as a guide to help us identify, assess and manage cybersecurity risks relevant to our business. In general, we seek to address cybersecurity risks through a comprehensive, cross-functional approach that is focused on preserving the confidentiality, security and availability of the information that we collect and store by identifying, preventing and mitigating cybersecurity threats and effectively responding to cybersecurity incidents when they occur.

Cybersecurity Risk Management and Strategy; Effect of Risk

We face risks related to cybersecurity such as unauthorized access, cybersecurity attacks and other security incidents, including as perpetrated by hackers and unintentional damage or disruption to hardware and software systems, loss of data, and misappropriation of confidential information. To identify and assess material risks from cybersecurity threats, we maintain a cybersecurity program designed to ensure our systems are effective and prepared for information security risks, including regular oversight of our programs for security monitoring for internal and external threats to ensure the confidentiality and integrity of our information assets. We consider risks from cybersecurity threats alongside other company risks as part of our overall risk assessment process. We employ a range of tools and services, including regular network and endpoint monitoring, audits, vulnerability assessments, penetration testing, threat modeling and tabletop exercises to inform our risk identification and assessment. As discussed in more detail under "Cybersecurity Governance" below, our audit committee provides oversight of our cybersecurity risk management and strategy processes, which are led by our Chief Financial Officer, General Counsel, and Director of Information Technology.

We also identify our cybersecurity threat risks by comparing our processes to standards set by NIST and the International Organization for Standardization, as well as by engaging experts to attempt to infiltrate our information systems. To provide for the availability of critical data and systems, maintain regulatory compliance, manage our material risks from cybersecurity threats, and protect against and respond to cybersecurity incidents, we undertake the following activities:

a. monitor emerging data protection laws and implement changes to our processes that are designed to comply with such laws;
b. through our policies, practices and contracts (as applicable), require employees, as well as third parties that provide services on our behalf, to treat confidential information and data with care;
c. employ technical safeguards that are designed to protect our information systems from cybersecurity threats, including firewalls, intrusion prevention and detection systems, anti-malware functionality and access controls, which are evaluated and improved through vulnerability assessments and cybersecurity threat intelligence;
d. provide regular, mandatory training for our employees and contractors regarding cybersecurity threats as a means to equip them with effective tools to address cybersecurity threats, and to communicate our evolving information security policies, standards, processes and practices;
e. conduct regular phishing email simulations for all employees and contractors with access to our email systems to enhance awareness and responsiveness to possible threats;
f. conduct annual cybersecurity management and incident training for employees involved in our systems and processes that handle sensitive data;

g. run tabletop exercises to simulate a response to a cybersecurity incident and use the findings to improve our processes and technologies; and
h. carry information security risk insurance that provides protection against the potential losses arising from a cybersecurity incident.

Our incident response plan coordinates the activities we take to prepare for, detect, respond to and recover from cybersecurity incidents, which include processes to triage, assess severity for, escalate, contain, investigate and remediate the incident, as well as to comply with potentially applicable legal obligations and mitigate damage to our business and reputation.

As part of the above processes, we regularly engage with consultants, auditors and other third parties, including annually having an independent third-party review our cybersecurity program to help identify areas for continued focus, improvement and compliance.

Our processes also address cybersecurity threat risks associated with our use of third-party service providers, including our suppliers and manufacturers or who have access to patient and employee data or our systems. In addition, cybersecurity considerations affect the selection and oversight of our third-party service providers. We perform diligence on third parties that have access to our systems, data or facilities that house such systems or data, and continually monitor cybersecurity threat risks identified through such diligence. Additionally, we generally require those third parties that could introduce significant cybersecurity risk to us to agree by contract to manage their cybersecurity risks in specified ways, and to agree to be subject to cybersecurity audits, which we conduct as appropriate.

We describe whether and how risks from identified cybersecurity threats, including as a result of any previous cybersecurity incidents, have materially affected or are reasonably likely to materially affect us, including our business strategy, results of operations, or financial condition, under the heading "*Cybersecurity breaches could expose us to material liability, damage our reputation, compromise our confidential information or otherwise adversely affect our business,*" which disclosures are incorporated by reference herein.

In the last two fiscal years, we have not experienced any material cybersecurity incidents and the expenses we have incurred from cybersecurity incidents were immaterial. This includes penalties and settlements, of which there were none.

Cybersecurity Governance; Management

Cybersecurity is an important part of our risk management processes and an area of focus for our board of directors and management. The audit committee of our board of directors is responsible for the oversight of risks from cybersecurity threats.

At least annually, our audit committee receives an update from management of our cybersecurity threat risk management and strategy processes covering topics such as data security posture, results from third-party assessments, progress towards predetermined risk-mitigation-related goals, our incident response plan, and material cybersecurity threat risks or incidents and developments, as well as the steps management has taken to respond to such risks. In such sessions, our audit committee generally receives materials discussing current and emerging material cybersecurity threat risks, and describing our ability to mitigate those risks, as well as recent developments, evolving standards, technological developments and information security considerations arising with respect to our peers and third parties, and discusses such matters with our Director of Information Technology. Our audit committee also receives prompt and timely information regarding any cybersecurity incident that meets establishing reporting thresholds, as well as ongoing updates regarding any such incident until it has been addressed.

Our cybersecurity risk management and strategy processes, which are discussed in greater detail above, are led primarily by our Director of Information Technology, who has several years of prior work experience in various roles involving managing information security, developing cybersecurity strategy, and implementing effective information and cybersecurity programs. Our Director of Information Technology is informed with regard to and monitors the prevention, mitigation, detection, and remediation of cybersecurity incidents through his management of, and participation in, the cybersecurity risk management and strategy processes described above, including the

operation of our incident response plan. As discussed above, our management team reports to the audit committee of our board of directors about cybersecurity threat risks, among other cybersecurity related matters, at least annually.

Item 2. Properties.

Our headquarters are located in La Jolla, California where we currently lease approximately 43,000 square feet of laboratory and office space under a lease that expires in 2028. We have an option to extend the lease an additional three years. We believe that this space is sufficient to meet our needs for the foreseeable future and that any additional space we may require will be available on commercially reasonable terms.

Item 3. Legal Proceedings.

Except as disclosed below, we are not currently a party to any material legal proceedings. From time to time, we may become involved in legal proceedings arising in the ordinary course of our business. Regardless of outcome, litigation can have an adverse impact on us due to defense and settlement costs, diversion of management resources, negative publicity, reputational harm and other factors.

In November 2024, the Company was successful in the trade secrets case brought against it by I-Mab Biopharma in the United States District Court for the District of Delaware, with the jury rejecting all allegations of misappropriation before it. In January 2025, the parties reached a settlement as to all asserted claims of misappropriation, including those claims not tried to the jury. Pursuant to that agreement, the Court dismissed the action with prejudice.

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

Market Information

Our common stock is traded on the Nasdaq Global Market under the ticker symbol "INBX."

Holders of Common Stock

As of February 28, 2025, we had 14,475,904 outstanding shares of common stock and approximately 6 holders of record of our common stock. The approximate number of holders is based upon the actual number of holders registered in our records at such date and excludes holders in "street name" or persons, partnerships, associations, corporations, or other entities identified in security positions listings maintained by depository trust companies.

Dividend Policy

We have never declared or paid cash dividends on our capital stock. We intend to retain all available funds and future earnings, if any, for use in the operation of our business and do not anticipate paying any cash dividends on our common stock in the foreseeable future. Any future determination to declare and pay dividends will be made at the discretion of our board of directors and will depend on various factors, including applicable laws, our results of operations, our financial condition, our capital requirements, general business conditions, our future prospects, restrictions in our debt agreements and other factors that our board of directors may deem relevant. In addition, the terms of the 2025 Loan Agreement restrict our ability to pay dividends without the prior written consent of Oxford. Investors should not purchase our common stock with the expectation of receiving cash dividends.

Securities Authorized for Issuance Under Equity Compensation Plans

See Item 12 of Part III of this Annual Report for information about our equity compensation plans which is incorporated by reference herein.

Recent Sales of Unregistered Securities

None.

Purchases 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 related notes appearing elsewhere in this Annual Report. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report contains forward-looking statements that involve risk and uncertainties, including those described in the section of this Annual Report titled "Special Note Regarding Forward-Looking Statements." As a result of many factors, including those factors set forth in the section of this Annual Report titled "Risk Factors," our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are a clinical-stage biopharmaceutical company with a pipeline of novel biologic therapeutic candidates, developed using our proprietary modular protein engineering platforms. We leverage our innovative protein engineering technologies and deep understanding of target biology to create therapeutic candidates with attributes and mechanisms we believe to be superior to current approaches and applicable to a range of challenging, validated targets with high potential.

Recent Developments

Separation from Former Parent

In January 2024, Inhibrx, Inc., or the Former Parent, announced its intent, as approved by its board of directors, to effect the spin-off of INBRX-101, an optimized, recombinant alpha-1 antitrypsin, or AAT, augmentation therapy in a registrational trial for the treatment of patients with alpha-1 antitrypsin deficiency. On May 29, 2024, the Former Parent completed a distribution to holders of its shares of common stock of 92% of the issued and outstanding shares of common stock of the Company, or the Distribution. On May 30, 2024, the Former Parent completed a series of internal restructuring transactions, or the Separation.

On May 30, 2024, the Former Parent completed the merger, or the Merger, of Art Acquisition Sub, Inc., a wholly-owned subsidiary of Aventis Inc., or the Acquirer, a wholly-owned subsidiary of Sanofi S.A., or Sanofi, with and into the Former Parent with the Former Parent continuing as the surviving entity. Pursuant to the Merger (i) all assets and liabilities primarily related to INBRX-101, or the 101 Business, were transferred to the Acquirer; and (ii) by way of the Separation, the Company acquired the assets and liabilities and corporate infrastructure associated with its ongoing programs, INBRX-106 and ozekibart (INBRX-109), and its discovery pipeline, as well as the remaining close-out obligations related to its previously terminated program, INBRX-105.

Upon the closing, each Former Parent stockholder received: (i) $30.00 per share in cash, (ii) one contingent value right per share, representing the right to receive a contingent payment of $5.00 in cash upon the achievement of a regulatory milestone, and (iii) one SEC-registered, publicly listed, share of Inhibrx for every four shares of the Former Parent's common stock held.

From and after the closing, Inhibrx continues to operate as a stand-alone, publicly traded company focused on ozekibart (INBRX-109) and INBRX-106, both of which are clinical-stage programs.

For periods prior to the spin-off, descriptions of historical business activities are presented as if the spin-off had already occurred, and the Former Parent's activities related to such assets and liabilities had been performed by the Company. Refer to Note 1 to our consolidated financial statements included elsewhere in this Annual Report for further discussion of the underlying basis used to prepare the consolidated financial statements. The operating results presented in the Company's historical financial statements prior to the Merger and in connection with the Separation and the Merger may not be indicative of the results of the Company following the Merger and Separation.

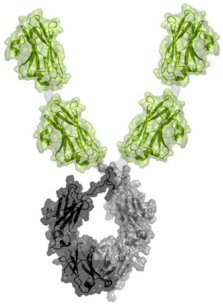
Transactions with Related Parties

We entered into a Separation and Distribution Agreement and various agreements relating to transition services, licenses and certain other matters with the Former Parent, which govern our relationship with the Former Parent prior to, at and after the Former Parent completed the Distribution. These agreements include the allocation of

employee benefits, taxes and certain other liabilities and obligations attributable to periods prior to, at and after the Distribution. The terms of these agreements, including amounts billed during the period, are discussed in greater detail in Note 7 to our consolidated financial statements included elsewhere in this Annual Report.

Current Clinical Pipeline

Our current clinical pipeline of therapeutic candidates includes ozekibart (INBRX-109) and INBRX-106, both of which utilize our multivalent formats where the precise valency can be optimized in a target-centric way to mediate what we believe to be the most appropriate agonist function:



ozekibart (INBRX-109)
Tetravalent DR5 agonist



INBRX-106
Hexavalent OX40 agonist

Program	Therapeutic Area	Target(s)/Format	STAGE OF DEVELOPMENT
			Preclinical / Phase 1 / Phase 2 / Phase 3
ozekibart (INBRX-109)*	Oncology	DR5 Tetravalent Agonist	
INBRX-106**	Oncology	OX40 Hexavalent Agonist	

* Currently being investigated in chondrosarcoma, Ewing sarcoma, and colorectal cancer.
** Currently being investigated in patients with non-small cell lung cancer, or NSCLC, and head and neck squamous cell carcinoma, or HNSCC.

ozekibart (INBRX-109)

ozekibart (INBRX-109) is a tetravalent death receptor 5, or DR5, agonist currently being evaluated in patients diagnosed with chondrosarcoma, colorectal cancer, and Ewing sarcoma.

Chondrosarcoma

In June 2021, based on the initial Phase 1 data results, we initiated a registration-enabling Phase 2 trial for the treatment of unresectable or metastatic conventional chondrosarcoma for which the United States Food and Drug Administration, or FDA, and the European Medicines Agency, or EMA, granted orphan drug designation in November 2021 and August 2022, respectively. The primary endpoint for this Phase 2 trial is progression-free survival, or PFS. Data from the registration-enabling Phase 2 trial in unresectable or metastatic conventional chondrosarcoma is expected during the third quarter of 2025.

Ewing sarcoma

In November 2023, we announced interim efficacy and safety data from the cohort of the Phase 1 trial evaluating ozekibart (INBRX-109) in combination with Irinotecan, or IRI, and Temozolomide, or TMZ, for the treatment of advanced or metastatic, unresectable Ewing sarcoma. Overall, ozekibart (INBRX-109) in combination with IRI/TMZ was well tolerated from a safety perspective. Based on this preliminary data, the ongoing Phase 1/2 trial in the Ewing sarcoma cohort was expanded. Interim data on this cohort are anticipated during the second half of 2025.

Colorectal adenocarcinoma

In January 2025, we announced interim efficacy and safety data from the cohort of the Phase 1 trial evaluating ozekibart (INBRX-109) in combination with FOLFIRI for the treatment of advanced or metastatic, unresectable colorectal adenocarcinoma, or CRC. Efficacy was assessed in 10 of the 13 patients evaluable as of the cutoff date of December 2, 2024, who received at least one dose of ozekibart, based on RECIST v1.1 criteria. We have expanded recruitment of this cohort by 50 patients as a result of these preliminary findings in order to validate these findings in a more uniform patient population. Data on this cohort are anticipated in the third quarter of 2025.

INBRX-106

INBRX-106 is a precisely engineered hexavalent sdAb-based therapeutic candidate targeting OX40, designed to be an optimized agonist of this co-stimulatory receptor. It is currently being investigated as a single agent and in combination with Keytruda in patients with locally advanced or metastatic solid tumors. Parts 1 and 3, dose escalation as a single agent and in combination with Keytruda, have been completed. We observed durable responses across multiple tumor types.

In Part 4 of the Phase 1/2 trial, we continue to enroll patients with NSCLC and HNSCC, both in combination with Keytruda. Primary endpoints for these cohorts are objective response rate, or ORR, disease control rate, or DCR, duration of response, or DOR, and safety. In addition, a new cohort has been initiated in NSCLC to evaluate chemotherapy when used in conjunction with the INBRX-106 and Keytruda combination. The primary endpoint for this cohort is safety. We expect to have a more mature dataset on these cohorts during the fourth quarter of 2025 and plan to provide an update at that time.

In June 2024, a seamless Phase 2/3 clinical trial was initiated for INBRX-106 in combination with Keytruda as a first-line treatment for patients with local advanced recurrent or metastatic head HNSCC. This trial recruits patients who have not received prior checkpoint inhibitors and whose tumors express a PDL-1 CPS equal to or greater than 20. We plan to enroll approximately 60 patients in the Phase 2 portion with a primary endpoint of ORR supported by secondary endpoints of DOR, PFS, and safety. We expect to announce initial data on Phase 2 during the fourth quarter of 2025. If positive, we anticipate this data will ungate the Phase 3 portion, where we expect approximately 350 patients will be randomized to INBRX-106 or placebo in combination with Keytruda. The co-primary endpoints for the Phase 3 portion of the study will be PFS and overall survival.

Components of Results of Operations

Revenue

As of the date of this Annual Report, all of our revenue has been derived from licenses with collaboration partners and grant awards. We have not generated any revenue from the commercial sale of approved therapeutic products to date.

Operating Expenses

Research and Development

As of the date of this Annual Report, our research and development expenses have related primarily to research activities, including our discovery efforts, and preclinical and clinical development and the manufacturing of our therapeutic candidates. Research and development expenses are recognized as incurred and payments made prior to the receipt of goods or services to be used in research and development are capitalized until the goods or services are received.

In accordance with the applicable accounting and regulatory requirements, we track all research and development expenses in the aggregate and do not manage or track either external or internal expenses on a program-by-program

basis. External research and development expenses are instead managed and tracked by the nature of the activity, and primarily consist of contract manufacturing and clinical trial expenses. Internal research and development expenses primarily relate to personnel, early research and consumable costs, which are deployed across multiple projects under development. We manage and prioritize our research and development expenses based on scientific data, probability of successful technical development and regulatory approval, market potential and unmet medical need, among other considerations. We regularly review our research and development activities and, as necessary, reallocate resources that we believe will best support the long-term growth of our overall business. We review expenses incurred by vendor and by contract as benchmarked against the progression of our clinical and other milestones.

External research and development expenses consist of:

- expenses incurred in connection with the preclinical development of our programs;
- clinical trials of our therapeutic candidates, including under agreements with third parties, such as consultants and contract research organizations, or CROs;
- expenses associated with the manufacturing of our therapeutic candidates under agreements with contract development and manufacturing organizations, or CDMOs;
- expenses associated with regulatory requirements, including fees and other expenses related to our Scientific Advisory Board; and
- other external expenses, such as laboratory services related to our discovery and development programs and other shared services.

Internal research and development expenses consist of:

- salaries, benefits and other related costs, including non-cash stock-based compensation under the former Amended and Restated 2017 Employee, Director and Consultant Equity Incentive Plan, or the 2017 Plan, and the 2024 Omnibus Incentive Plan, or the 2024 Plan, for personnel engaged in research and development functions;
- facilities, depreciation and other expenses, which include direct and allocated expenses for depreciation and amortization, rent and maintenance of facilities; and
- other internal expenses, such as laboratory supplies and other shared research and development costs.

We expect that research and development expense will continue to increase over the next several years as we continue development of our therapeutic candidates currently in clinical stage development and support our preclinical programs. In particular, clinical development of our therapeutic candidates, as opposed to preclinical development, generally has higher development costs, primarily due to the increased size and duration of later-stage clinical trials. Moreover, the costs associated with our CDMOs to manufacture our therapeutic candidates and future commercial products is also much more costly as compared to early-stage preclinical development. We cannot determine with certainty the timing of initiation, the duration or the completion costs of current or future preclinical studies and clinical trials of our therapeutic candidates due to the inherently unpredictable nature of preclinical and clinical development. Preclinical and clinical development timelines, the probability of success and development costs can differ materially from expectations. We anticipate that we will make determinations as to which therapeutic candidates to pursue and how much funding to direct to each therapeutic candidate on an ongoing basis in response to the results of ongoing and future preclinical studies and clinical trials, regulatory developments, and our ongoing assessments as to each therapeutic candidate's commercial potential. We will need substantial additional capital in the future to support these efforts. In addition, we cannot forecast which therapeutic candidates may be subject to future collaborations, when such arrangements will be secured, if at all, and to what degree such arrangements would affect our development plans and capital requirements.

Our clinical development costs may vary significantly based on factors such as:

- the per patient trial costs;
- the number of trials required for approval;
- the number of sites included in the trials;
- the countries in which the trials are conducted;

- the length of time required to enroll eligible patients;
- the number of patients that participate in the trials;
- the ability to identify patients eligible for our clinical trials;
- the number of doses that patients receive;
- the drop-out or discontinuation rates of patients;
- the potential additional safety monitoring requested by regulatory agencies;
- the duration of patient participation in the trials and follow-up;
- the cost, timing, and successful manufacturing of our therapeutic candidates;
- the phase and development of our therapeutic candidates;
- the efficacy and safety profile of our therapeutic candidates;
- the timing, receipt, and terms of any approvals from applicable regulatory authorities including the FDA and non-U.S. regulators;
- maintaining a continued acceptable safety profile of our therapeutic candidates following approval, if any;
- significant and changing government regulation and regulatory guidance;
- the ability to attract and retain personnel;
- the impact of any business interruptions to our operations or to those of the third parties with whom we work;
- the uncertainties related to potential economic downturn, inflation, interest rates, geopolitical events and widespread health events on capital and financial markets, the supply chain and our expenses; and
- the extent to which we establish additional strategic collaborations or other arrangements.

General and Administrative

General and administrative, or G&A, expenses consist primarily of:

- salaries, benefits and other related costs, including non-cash stock-based compensation under the former 2017 Plan and 2024 Plan, for personnel engaged in G&A functions;
- expenses incurred in connection with accounting, audit, and tax services, legal services, including costs associated with obtaining and maintaining our patent portfolio, investor relations and consulting expenses under agreements with third parties, such as consultants and contractors;
- expenses incurred in connection with commercialization and business development activity; and
- facilities, depreciation and other expenses, which include direct and allocated expenses for depreciation and amortization, rent and maintenance of facilities, insurance and supplies.

During the year ended December 31, 2024, we incurred increased G&A expenses in connection to the Merger, including stock compensation expense upon acceleration of options, and other transaction costs, including legal, advisory, and consulting services. We do not expect these expenses to recur in future years. We expect certain of our G&A expenses will continue to increase in the future to support our continued research and development activities, including costs related to pre-commercialization and business development activities. Additionally, we will continue to incur other professional service fees, including but not limited to, legal costs associated with the filing, prosecution, and maintenance of our patents for our therapeutic candidates, and other legal matters, as well as costs associated with services for compliance, accounting, legal, regulatory, tax, investor and public relations.

Other Income (Expense)

Gain related to transaction with Acquirer. Gain related to transaction with Acquirer consists of our gain recorded in connection with the completion of the Merger during the second quarter of 2024. We do not expect future gains in connection with the Merger in future periods.

Interest expense. Interest expense consists of interest on our former loans with Oxford incurred prior to the Merger, upon which the outstanding debt was assumed by the Acquirer. In future periods, we expect to incur interest expense in connection with our loan and security agreement with Oxford Finance LLC and other lenders, or collectively, Oxford, entered into in January 2025, or the 2025 Loan Agreement.

Interest income. Interest income consists of interest earned on cash and cash equivalents, which include sweep and money market account balances as well as investments held in highly liquid debt securities with original maturities of less than three months from our date of acquisition.

Loss on Equity Method Investment

Our equity interest in Phylaxis BioScience, LLC, or Phylaxis, is accounted for as an equity method investment and the Company's proportionate share of the net income or loss of Phylaxis is included as loss in equity method investment in the consolidated statement of operations.

Results of Operations

Comparison of Years Ended December 31, 2024 and December 31, 2023

The following table summarizes our consolidated results of operations for each of the periods indicated (in thousands, except percentages):

	YEAR ENDED DECEMBER 31,		CHANGE	
	2024	2023	($)	(%)
Revenue:				
License fee revenue	$ 200	$ 1,800	$ (1,600)	(89)%
Total revenue	200	1,800	(1,600)	(89)%
Operating expenses:				
Research and development	203,743	191,640	12,103	6 %
General and administrative	127,905	29,381	98,524	335 %
Total operating expenses	331,648	221,021	110,627	50 %
Loss from operations	(331,448)	(219,221)	(112,227)	51 %
Other income (expense):				
Gain related to transaction with Acquirer	2,021,498	—	2,021,498	100 %
Interest expense	(13,491)	(31,840)	18,349	(58)%
Interest income	10,940	11,917	(977)	(8)%
Other income (expense), net	75	(580)	655	(113)%
Total other income (expense)	2,019,022	(20,503)	2,039,525	(9,947)%
Provision for income taxes	2	3	(1)	(33)%
Loss on equity method investment	—	1,634	(1,634)	(100)%
Net income (loss)	$ 1,687,572	$ (241,361)	$ 1,928,933	(799)%

License Fee Revenue

License fee revenue during the year ended December 31, 2024 was $0.2 million and consisted of revenue related to our license agreement with Regeneron Pharmaceuticals, Inc., which we recognized following the grant of two six-month extensions of the option term during the year, each for revenue of $0.1 million. License fee revenue during the year ended December 31, 2023 was $1.8 million and consisted of $1.6 million of revenue related to our agreements with Phylaxis and $0.2 million of revenue related to a former option agreement which was completed during 2023. The revenue under our Phylaxis arrangement was earned following the transfer of a second-generation compound to Phylaxis during the year ended December 31, 2023, upon which we received an additional 5% equity interest in Phylaxis, which we recognized as revenue at its fair value of $1.6 million. See Note 6 to our consolidated financial statements included elsewhere in this Annual Report for additional information on our license and collaboration agreements.

Research and Development Expense

The following table sets forth the primary external and internal research and development expenses (in thousands, except percentages):

	YEAR ENDED DECEMBER 31,		CHANGE	
	2024	2023	($)	(%)
External expenses:				
Contract manufacturing	$ 55,643	$ 77,248	$ (21,605)	(28)%
Clinical trials	47,665	42,960	4,705	11 %
Other external research and development	11,691	10,440	1,251	12 %
Internal expenses:				
Personnel	72,790	47,818	24,972	52 %
Equipment, depreciation, and facility	9,693	7,401	2,292	31 %
Other internal research and development	6,261	5,773	488	8 %
Total research and development expenses	$ 203,743	$ 191,640	$ 12,103	6 %

Research and development expense increased by $12.1 million from $191.6 million during the year ended December 31, 2023 to $203.7 million during the year ended December 31, 2024. The overall increase was primarily due to the following factors:

- contract manufacturing expense decreased by $21.6 million due to the nature of the development and manufacturing activities performed during each period at our CDMO and CRO partners supporting our clinical and preclinical therapeutic candidates, primarily due to the divestiture of INBRX-101, for which we incurred significant expenses during the year ended December 31, 2023 related to large scale drug substance manufacturing services performed by one of our CDMO partners including the utilization of raw materials;
- clinical trial expense increased by $4.7 million primarily due to the expansion of our ongoing registration-enabling Phase 2 trial for ozekibart (INBRX-109) for the treatment of unresectable or metastatic conventional chondrosarcoma and due to the expansion of our INBRX-106 Phase 1/2 trial and initiation of the Phase 2/3 trial for HNSCC, including expenses for in-house clinical trial support, as well as costs incurred for our registration-enabling Phase 2 trial for INBRX-101 for the treatment of emphysema due to AATD, prior to our spin-off of the INBRX-101 program during the period. These expenses were offset in part by reduced clinical expenses following the termination of our INBRX-105 program;
- personnel-related expense increased by $25.0 million, which was primarily related to $25.9 million in stock option expense recognized upon the acceleration of outstanding options in connection with the closing of the Merger;
- facility and equipment-related expense increased by $2.3 million, which was attributable to expenses related to capitalized software placed in service during the period; and
- other research and development expense increased by $1.7 million, which was primarily attributable to an increase in clinical-related consulting expenses and the purchase of lab supplies, offset in part by decreases in costs associated with preclinical studies.

G&A Expense

G&A expense increased by $98.5 million from $29.4 million during the year ended December 31, 2023 to $127.9 million during the year ended December 31, 2024. The overall increase was primarily due to the following factors:

- one-time expenses incurred related to the Merger of $68.1 million, consisting of legal, advisory, and consulting services performed in connection to the transaction, and SEC filing fees in connection with filings related to the transaction;
- personnel-related expenses increased by $19.9 million, which was primarily related to $15.2 million in stock option expense recognized upon the acceleration of outstanding options in connection with the close of the Merger, in addition to other bonuses paid in connection with the Merger;

- professional fees for legal services increased by $8.2 million, which was primarily attributable to costs incurred in connection with legal proceedings, which have since concluded, finding us not liable for damages, and other intellectual property matters;
- pre-commercialization expenses increased by $1.7 million, primarily related to increases in consulting services and scientific publications to support our commercial operations business intelligence strategies related to ozekibart (INBRX-109) and prior to the Merger, related to INBRX-101, in addition to a focus on patient advocacy and recruitment efforts, offset in part by a decrease in market research efforts following the disposition of INBRX-101; and
- facility and equipment-related expense increased by $0.6 million, which was primarily attributable to an increase in software subscriptions and tenant improvements during the current year.

Other Income (Expense)

Gain related to transaction with Acquirer. During the year ended December 31, 2024, we earned $2.0 billion of other income, consisting of gains recorded in connection with the completion of the Merger. We recorded a gain of $1.7 billion related to Merger consideration for our outstanding common stock, warrants, and stock options, in addition to $211.3 million related to the extinguishment of our loan under an amended loan agreement with Oxford, or the Amended 2020 Loan Agreement, which loan was assumed by the Acquirer. In addition to the Acquirer assuming our outstanding debt, the Acquirer assumed outstanding assets and liabilities related to INBRX-101 upon the transaction, resulting in a gain of $14.5 million. The Acquirer also reimbursed us for or paid on our behalf $68.0 million of transaction costs related to the Merger, resulting in a gain. We do not expect future income or gains in connection with the Merger in future periods.

Interest expense. Interest expense decreased by $18.3 million from $31.8 million during the year ended December 31, 2023 to $13.5 million during the year ended December 31, 2024, all of which relates to interest incurred and the amortization of debt discounts related to the Amended 2020 Loan Agreement. The decrease in interest expense is the result of the extinguishment of the Amended 2020 Loan Agreement in connection with the Merger. We did not incur any interest following the close of the Merger on May 30, 2024, the date upon which the Acquirer assumed our outstanding debt.

Interest income. During the year ended December 31, 2024, we earned $10.9 million of interest income on our sweep and money market account balances. During the year ended December 31, 2023, we earned $11.9 million of interest income, of which $7.5 million related to interest earned on our sweep and money market account balances and $4.4 million related to the accretion of discount on investments in debt securities during the period.

Income Taxes

Income tax expense was approximately $2,000 and $3,000 during the years ended December 31, 2024 and December 31, 2023, respectively. For the years ended December 31, 2024 and December 31, 2023, we have applied a 100% valuation allowance against our federal deferred tax assets since it is more likely than not that the deferred tax assets will not be realized.

Loss on Equity Method Investment

During the year ended December 31, 2023, we received an additional 5% equity interest in Phylaxis following the achievement of a milestone under our agreements. Upon receipt of the equity interest, we established an equity method investment at its fair value of $1.6 million. The loss on equity method investment during the year ended December 31, 2023 of $1.6 million consists of our share of losses from our investment in Phylaxis, which reduced our equity investment to zero. During the year ended December 31, 2024, we did not record any gain or loss on our equity method investment.

Liquidity and Capital Resources

Sources of Liquidity

As of the date of this Annual Report, sources of capital raised to fund our operations have been comprised of the sale of equity securities, borrowings under loan and security agreements, payments received from commercial partners

for licensing rights to our therapeutic candidates under development, grants, and proceeds from the sale and issuance of convertible promissory notes.

In January 2025, we entered into the 2025 Loan Agreement with Oxford, upon which we received gross proceeds of $100.0 million. The 2025 Loan Agreement provides for up to an additional $50.0 million to be funded upon our request and at Oxford's sole discretion.

Future Funding Requirements

Since our inception, we have devoted substantially all of our efforts to therapeutic drug discovery and development, conducting preclinical studies and clinical trials, enabling manufacturing activities in support of our therapeutic candidates, pre-commercialization activities, organizing and staffing the Company, establishing our intellectual property portfolio, and raising capital to support and expand these activities. Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our outstanding accounts payable and accrued expenses. Our net income or losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of our clinical trials and our expenditures on other research and development activities, as well as the timing of other corporate transactions. During the year ended December 31, 2024, we had net income of $1.7 billion following the closing of the Merger, and during the year ended December 31, 2023, our net loss was $241.4 million. As of December 31, 2024, we had an accumulated deficit of $106.1 million and cash and cash equivalents of $152.6 million.

Based upon our current operating plans, we believe that our existing cash and cash equivalents will be sufficient to fund our operations for at least the next 12 months from the date of filing of this Annual Report. Our forecast of the period through which our financial resources will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties, and actual results could vary materially. We have based this estimate on assumptions that may prove to be wrong, and we could deplete our capital resources sooner than we expect.

The process of conducting preclinical studies and testing therapeutic candidates in clinical trials is costly, and the timing of progress and expenses in these studies and trials is uncertain. Though we had net income during the year ended December 31, 2024 following the Merger, we expect to continue to incur net losses for the foreseeable future until, if ever, we have an approved product and can successfully commercialize it. We expect our research and development expenses to increase as we continue our development of, and seek marketing approvals for, our therapeutic candidates (especially as we move more candidates into later stages of clinical development), and begin to commercialize any approved products, if ever. At this time, we are preparing to proceed with the commercialization of certain of our therapeutic candidates, if ever approved. As a result, we will incur significant pre-commercialization expenses in preparation for launch, the outcome of which is uncertain. Additionally, if approved, we will incur significant commercialization expenses related to product sales, marketing, manufacturing, and distribution. We also expect additional general and administrative expenses as we hire additional personnel and incur increased accounting, audit, legal, regulatory and compliance, investor and public relations expense to support our continued expansion.

Until such time we, if ever, can generate substantial product revenue, we expect to finance our cash needs through equity offerings, debt financings or other capital sources, including strategic licensing and collaborations, strategic transactions, or other similar arrangements and transactions, and from time to time, we engage in discussions with potential acquirers regarding the disposition of one or more of our therapeutic candidates. If the Company does raise additional capital through public or private equity or convertible debt offerings, the ownership interests of its existing stockholders will be diluted, and the terms of those securities may include liquidation or other preferences that adversely affect its stockholders' rights. If the Company raises capital through additional debt financings, such as our 2025 Loan Agreement with Oxford, it may be subject to covenants limiting or restricting its ability to take specific actions, such as incurring additional debt or making certain capital expenditures. To the extent that the Company raises additional capital through strategic licensing, collaboration or other similar agreements, it may have to relinquish valuable rights to its therapeutic candidates, future revenue streams or research programs at an earlier stage of development or on less favorable terms than it would otherwise choose, or to grant licenses on terms that may not be favorable to the Company. However, there can be no assurance as to the availability or terms upon which such finances or capital might be available in the future. If we are unable to secure adequate additional funding, we will need to reevaluate our operating plan and may be forced to make reductions in spending, extend payment terms

with suppliers, liquidate assets where possible, delay, scale back or eliminate some or all of our development programs, or relinquish rights to our intellectual property on less favorable terms than we would otherwise choose. These actions could materially impact our business, results of operations, financial condition, and prospects.

Our future liquidity and capital funding requirements will depend on numerous factors, including:

- the outcome, costs and timing of preclinical studies and clinical trials for our current or future therapeutic candidates;
- whether and when we are able to obtain marketing approval to market any of our therapeutic candidates and the outcome of meetings with applicable regulatory agencies, including the FDA;
- our ability to successfully commercialize, including the costs and timing of manufacturing, any therapeutic candidates that receive marketing approval;
- the emergence and effect of competing or complementary therapeutics or therapeutic candidates;
- our ability to maintain, expand and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with the licensing, filing, prosecution, defense and enforcement of any patents or other intellectual property rights;
- our ability to retain our current employees and the need and ability to hire additional management and scientific and medical personnel;
- the costs and timing of establishing or securing sales and marketing capabilities if any current or future therapeutic candidate is approved;
- the terms and timing of any strategic licensing, collaboration or other similar agreement that we have established or may establish;
- our ability to achieve market acceptance, coverage and adequate reimbursement from third-party payors and adequate market share and revenue for any approved therapeutics;
- our ability to repay, refinance or restructure when payment is due any indebtedness we might incur, including in the event such indebtedness is accelerated;
- the valuation of our capital stock; and
- the continuing or future effects of a potential economic downturn, inflation, interest rates, geopolitical events, and widespread health events on capital and financial markets, the supply chain and our expenses.

We do not own or operate manufacturing and testing facilities for the production of any of our therapeutic candidates, nor do we have plans to develop our own manufacturing operations in the foreseeable future. We currently rely on a limited number of third-party contract manufacturers for all of our required raw materials, antibodies and other biologics for our preclinical research, clinical trials, and if and when applicable, commercial product, and employ internal resources to manage our manufacturing relationships with these third parties.

Commitments

As of December 31, 2024, our material cash requirements from known contractual and other obligations primarily relate to our lease obligations and services provided by our third party CROs and CDMOs.

Our lease for our laboratory and office space expires in 2028, with an option to extend for an additional three years. As of December 31, 2024, we have future minimum rental obligations under these leases of $9.6 million, of which $2.3 million and $7.3 million are current and non-current, respectively. For more information regarding these lease agreements, refer to Note 9 to the consolidated financial statements.

We enter into contracts in the normal course of business with CROs related to our ongoing preclinical studies and clinical trials and with CDMOs for clinical supplies and manufacturing scale-up activities. These contracts are generally cancellable, with notice, at our option. We have recorded accrued expenses of approximately $21.1 million in our consolidated balance sheets for expenditures incurred for R&D services performed at CROs, CDMOs, and other third-party organizations as of December 31, 2024.

Cash Flow Summary

The following table sets forth a summary of the net cash flow activity for each of the periods indicated (in thousands):

	YEAR ENDED DECEMBER 31,	
	2024	2023
Net cash used in operating activities	$ (194,409)	$ (193,309)
Net cash used in investing activities	(2,597)	(4,593)
Net cash provided by financing activities	71,678	201,961
Net increase (decrease) in cash	$ (125,328)	$ 4,059

Operating Activities

Net cash used in operating activities was $194.4 million during the year ended December 31, 2024 and consisted primarily of net income of $1.7 billion, adjusted for non-cash items. Non-cash adjustments primarily related to gains recorded upon the Merger of $2.0 billion. Other non-cash adjustments included accretion on our debt discount and the non-cash portion of interest expense related to our debt of $2.1 million, stock-based compensation expense, including expense related to the acceleration of options upon the Merger, of $58.5 million, depreciation and amortization of $2.3 million and non-cash lease expense of $1.9 million. Changes in operating assets and liabilities also contributed to the cash used in operating activities, primarily related to an increase in other non-current assets of $3.7 million due to prepayments and additional deposits we made to our CRO partners during the period. Additionally, the operating lease liability decreased by $1.4 million as a result of lease payments made throughout the period. These uses of cash were offset by increases in accrued expenses and other current liabilities of $35.9 million, an increase in accounts payable of $17.9 million, and a decrease in prepaid expenses of $3.0 million due to the timing of payments to our CRO and CDMO partners during the period, each of which excludes the liabilities related to INBRX-101 which were assumed by the Acquirer in the Merger.

Net cash used in operating activities was $193.3 million during the year ended December 31, 2023 and consisted primarily of a net loss of $241.4 million, adjusted for non-cash items including stock-based compensation expense of $24.8 million, accretion on our debt discount and the non-cash portion of interest expense related to our debt of $4.9 million, depreciation and amortization of $1.2 million, and non-cash lease expense of $1.8 million. Non-cash revenue of $1.6 million earned in relation to the equity interest in Phylaxis received during the period was offset by the loss on equity method investment of $1.6 million reflecting our share of losses in Phylaxis. Changes in operating assets and liabilities also contributed to the cash used in operating activities, including an increase in prepaid expenses of $10.3 million, primarily due to the prepayment for clinical drug substance manufacturing services at our CDMOs during the year. Additionally, the operating lease liability decreased by $1.9 million as a result of lease payments made throughout the year. Receivables increased by $0.5 million, primarily as a result of dividends earned and not received as of December 31, 2023. Deferred revenue decreased by $0.2 million following the recognition of $0.2 million of previously deferred revenue related to our former option agreement. These uses of cash were offset by an increase in accrued expenses of $26.1 million and an increase in accounts payable of $2.1 million, primarily due to the timing of clinical drug substance manufacturing services incurred at our CDMOs and clinical activities incurred at our CROs, in addition to increases in compensation-related accruals as related to employee bonuses.

Investing Activities

Net cash used in investing activities was $2.6 million and $4.6 million during the years ended December 31, 2024 and December 31, 2023, respectively, and was related to capital purchases of software, leasehold improvements, and laboratory and office equipment.

Financing Activities

Net cash provided by financing activities was $71.7 million during the year ended December 31, 2024 and consisted of proceeds of $71.7 million received from the exercise of stock options.

Net cash provided by financing activities was $202.0 million during the year ended December 31, 2023 and consisted primarily of proceeds of $200.0 million from the issuance of common stock and pre-funded warrants in a

private placement transaction, offset in part by issuance costs of $0.4 million. In addition, we received proceeds of $2.3 million from the exercise of stock options.

Critical Accounting Estimates

Our consolidated financial statements and accompanying notes are prepared in accordance with United States generally accepted accounting principles, or GAAP, which requires management to make estimates and assumptions that affect the amounts reported. Management bases its estimates on historical experience, market and other conditions, and various other assumptions it believes to be reasonable. Although these estimates are based on management's best knowledge of current events and actions that may impact us in the future, the estimation process is, by its nature, uncertain given that estimates depend on events over which we may not have control. If market and other conditions change from those that we anticipate, our consolidated financial statements may be materially affected. In addition, if our assumptions change, we may need to revise our estimates, or take other corrective actions, either of which may also have a material effect in our consolidated financial statements. We review our estimates, judgments, and assumptions used in our accounting practices periodically and reflect the effects of revisions in the period in which they are deemed to be necessary. We believe that these estimates are reasonable; however, our actual results may differ from these estimates.

While our significant accounting policies are described in more detail in Note 1 to our consolidated financial statements included elsewhere in this Annual Report, we believe that the following critical accounting policies and estimates have a higher degree of inherent uncertainty and require our most significant judgments:

Accrued Research and Development and Clinical Trial Costs

We enter into contracts for research and development activities, including with CDMOs for clinical supplies and manufacturing scale-up activities related to our therapeutic candidates and with CROs for our preclinical studies and clinical trials. The financial terms of these agreements vary and may result in payment flows that do not match the periods over which materials or services are provided, resulting in either an accrual or a prepaid expense.

These accruals of research and development expenses require us to estimate expenses incurred, including estimates of the time period over which services will be performed, completion of contract components, the enrollment of subjects, and the status of our clinical trials. Such estimates are dependent upon the timeliness and accuracy of data provided by the CROs and CDMOs regarding the status and cost of the studies. If the actual timing of the performance of services varies from our estimates, we adjust the accrual or prepaid expense accordingly.

Although we do not expect our estimates to be materially different from amounts actually incurred, if our estimates of the status and timing of services performed differ from the actual status and timing of services performed, it could result in us reporting amounts that are too high or too low in any particular period. To date, there have been no material differences between our estimates of such expenses and the amounts actually incurred.

Emerging Growth Company

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act, or the JOBS Act, enacted in 2012. As such, we are eligible for exemptions from various reporting requirements applicable to other public companies that are not emerging growth companies, including, but not limited to, presenting only two years of audited financial statements, not being required to comply with the auditor attestation requirements of Section 404, reduced disclosure obligations regarding executive compensation, and an exemption from the requirements to obtain a non-binding advisory vote on executive compensation or golden parachute arrangements.

In addition, an emerging growth company can take advantage of an extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. We have irrevocably elected not to avail ourselves of this exemption and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

Smaller Reporting Company Status

Additionally, we are a "smaller reporting company," as defined in Rule 12b-2 under the Exchange Act. As such, we are eligible for exemptions from various reporting requirements applicable to other public companies that are not

smaller reporting companies, including, but not limited to, reduced disclosure obligations regarding executive compensation.

We will remain a smaller reporting company as long as either: (i) the market value of the shares of our common stock held by non-affiliates is less than $250.0 million as of the last business day of our most recently completed second fiscal quarter; or (ii) our annual revenue is less than $100.0 million during the most recently completed fiscal year and the market value of the shares of our common stock held by non-affiliates is less than $700.0 million as of the last business day of our most recently completed second fiscal quarter.

Recent Accounting Pronouncements

For information with respect to recently issued accounting standards and the impact of these standards, if any, on our consolidated financial statements, refer to Note 1 in our consolidated financial statements in Part II, Item 8 of this Annual Report.

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

Not applicable.

Item 8. Financial Statements and Supplementary Data.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

	Page
Report of Independent Registered Public Accounting Firm (BDO USA, P.C.; San Diego, California; PCAOB ID No. 243)	105
Consolidated Balance Sheets as of December 31, 2024 and December 31, 2023	106
Consolidated Statements of Operations for the Years Ended December 31, 2024 and December 31, 2023	107
Consolidated Statements of Stockholders' Equity for the Years Ended December 31, 2024 and December 31, 2023	108
Consolidated Statements of Cash Flows for the Years Ended December 31, 2024 and December 31, 2023	109
Notes to the Consolidated Financial Statements	111

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders

Inhibrx Biosciences, Inc.
La Jolla, California

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Inhibrx Biosciences, Inc. (the "Company") as of December 31, 2024 and 2023, the related consolidated statements of operations, stockholders' equity, and cash flows for each of 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 at December 31, 2024 and 2023, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's 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/ BDO USA, P.C.

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

San Diego, California

March 17, 2025

Inhibrx Biosciences, Inc.
Consolidated Balance Sheets
(In thousands, except share data and par value)

	AS OF DECEMBER 31,	
	2024	**2023**
Assets		
Current assets:		
Cash and cash equivalents	$ 152,596	$ 277,924
Accounts receivable	397	778
Receivables from related parties	23	—
Prepaid expenses and other current assets	7,382	16,656
Total current assets	160,398	295,358
Property and equipment, net	6,200	6,419
Operating right-of-use asset	7,338	2,952
Other non-current assets	6,831	3,164
Total assets	$ 180,767	$ 307,893
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 9,245	$ 10,954
Accrued expenses	29,890	43,295
Current portion of operating lease liability	1,595	2,063
Total current liabilities	40,730	56,312
Long-term debt, including final payment fee	—	206,968
Non-current portion of operating lease liability	6,453	1,110
Total liabilities	47,183	264,390
Commitments and contingencies (Note 10)		
Stockholders' equity:		
Preferred stock, $0.0001 par value, 15,000,000 shares authorized and no shares outstanding as of December 31, 2024 and December 31, 2023	—	—
Common stock, $0.0001 par value, 120,000,000 shares authorized as of December 31, 2024 and December 31, 2023; 14,475,904 and 47,369,511 shares issued and outstanding as of December 31, 2024 and December 31, 2023, respectively	1	5
Additional paid-in-capital	239,715	657,232
Accumulated deficit	(106,132)	(613,734)
Total stockholders' equity	133,584	43,503
Total liabilities and stockholders' equity	$ 180,767	$ 307,893

The accompanying notes are an integral part of these consolidated financial statements.

Inhibrx Biosciences, Inc.
Consolidated Statements of Operations
(In thousands, except per share data)

	YEAR ENDED DECEMBER 31,	
	2024	**2023**
Revenue:		
License fee revenue	$ 200	$ 1,800
Total revenue	200	1,800
Operating expenses:		
Research and development	203,743	191,640
General and administrative	127,905	29,381
Total operating expenses	331,648	221,021
Loss from operations	(331,448)	(219,221)
Other income (expense):		
Gain related to transaction with Acquirer	2,021,498	—
Interest expense	(13,491)	(31,840)
Interest income	10,940	11,917
Other income (expense), net	75	(580)
Total other income (expense)	2,019,022	(20,503)
Income (loss) before provision for income taxes	1,687,574	(239,724)
Provision for income taxes	2	3
Loss on equity method investment	—	1,634
Net income (loss)	$ 1,687,572	$ (241,361)
Earnings (loss) per share		
Basic	$ 114.01	$ (20.48)
Diluted	$ 112.62	$ (20.48)
Shares used in computing earnings (loss) per share		
Basic	14,802	11,783
Diluted	14,984	11,783

The accompanying notes are an integral part of these consolidated financial statements.

Inhibrx Biosciences, Inc.
Consolidated Statements of Stockholders' Equity
(In thousands)

	Common Stock (Shares)	Common Stock (Amount)	Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
Balance as of December 31, 2022	43,564	$ 4	$ 430,426	$ (372,373)	$ 58,057
Stock-based compensation expense	—	—	24,846	—	24,846
Issuance of shares upon exercise of stock options	184	—	2,316	—	2,316
Issuance of common stock and pre-funded warrants in private placement, net of issuance costs	3,621	1	199,644	—	199,645
Net loss	—	—	—	(241,361)	(241,361)
Balance as of December 31, 2023	47,369	$ 5	$ 657,232	$ (613,734)	$ 43,503
Stock-based compensation expense	—	—	58,518	—	58,518
Issuance of shares upon exercise of stock options	3,449	—	71,678	—	71,678
Issuance of shares upon exercise of warrants	2,746	—	—	—	—
Acquisition of Former Parent's common stock, stock options, and warrants by the Acquirer	(53,564)	(5)	(563,754)	(1,179,970)	(1,743,729)
Issuance of shares in Distribution	14,476	1	16,041	—	16,042
Net income	—	—	—	1,687,572	1,687,572
Balance as of December 31, 2024	14,476	$ 1	$ 239,715	$ (106,132)	$ 133,584

The accompanying notes are an integral part of these consolidated financial statements.

Inhibrx Biosciences, Inc.
Consolidated Statements of Cash Flows
(In thousands)

	YEAR ENDED DECEMBER 31,	
	2024	**2023**
Cash flows from operating activities		
Net income (loss)	$ 1,687,572	$ (241,361)
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Depreciation and amortization	2,285	1,191
Accretion of debt discount and non-cash interest expense	2,065	4,899
Stock-based compensation expense	58,518	24,846
Non-cash lease expense	1,897	1,765
Non-cash gain on transaction with Acquirer	(1,998,809)	—
Loss from equity method investment	—	1,634
Non-cash license revenue	—	(1,634)
Loss on disposal of fixed assets	12	3
Changes in operating assets and liabilities:		
Accounts receivable	381	(535)
Receivables from related parties	(23)	14
Prepaid expenses and other current assets	2,982	(10,285)
Other non-current assets	(3,667)	—
Accounts payable	17,903	2,109
Accrued expenses	35,883	26,071
Operating lease liability	(1,408)	(1,860)
Deferred revenue, current portion	—	(166)
Net cash used in operating activities	(194,409)	(193,309)
Cash flows from investing activities		
Purchase of fixed assets	(2,597)	(4,593)
Net cash used in investing activities	(2,597)	(4,593)
Cash flows from financing activities		
Proceeds from issuance of common stock and pre-funded warrants in private placement	—	200,000
Issuance costs associated with issuance of common stock and pre-funded warrants in private placement	—	(355)
Proceeds from exercise of stock options	71,678	2,316
Net cash provided by financing activities	71,678	201,961
Net increase (decrease) in cash	(125,328)	4,059
Cash and cash equivalents at beginning of period	277,924	273,865
Cash and cash equivalents at end of period	$ 152,596	$ 277,924

Supplemental disclosure of cash flow information				
Cash paid for interest	$	11,506	$	26,717
Cash paid for income taxes	$	2	$	3
Supplemental schedule of non-cash investing and financing activities				
Remeasurement of operating lease liability and right-of-use asset in connection with 2024 Lease Agreement	$	6,283	$	—
Payable for purchase of fixed assets	$	—	$	519

The accompanying notes are an integral part of these consolidated financial statements.

Inhibrx Biosciences, Inc.
Notes to Consolidated Financial Statements

1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Organization

Inhibrx Biosciences, Inc., or the Company, or Inhibrx, is a clinical-stage biopharmaceutical company focused on developing a broad pipeline of novel biologic therapeutic candidates. The Company combines target biology with protein engineering, technologies, and research and development to design therapeutic candidates. The Company's current pipeline is focused on oncology.

The Company is subject to risks and uncertainties common to early-stage companies in the biopharmaceutical industry, including, but not limited to, risks associated with preclinical studies, clinical trials and regulatory applications, development by competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, compliance with government regulations and the ability to secure additional capital to fund operations. The Company's therapeutic candidates currently under development will require significant additional research and development efforts, including clinical and preclinical testing and marketing approval prior to commercialization. These efforts require significant amounts of capital, adequate personnel and infrastructure and extensive compliance-reporting capabilities. Even if the Company's development efforts are successful, it is uncertain when, if ever, the Company will realize significant revenue from product sales.

Basis of Presentation

The accompanying consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America, or GAAP, and applicable rules and regulations of the Securities and Exchange Commission, or the SEC, related to an annual report on the Form 10-K.

Principles of Consolidation

The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiary and have been prepared in conformity with GAAP. All intercompany accounts and transactions have been eliminated in consolidation.

Separation and Distribution

In January 2024, Inhibrx, Inc., or the Former Parent, announced its intent, as approved by its board of directors, to effect the spin-off of INBRX-101, an optimized, recombinant alpha-1 antitrypsin, or AAT, augmentation therapy in a registrational trial for the treatment of patients with alpha-1 antitrypsin deficiency. The Former Parent and the Company signed an Agreement and Plan of Merger, dated as of January 22, 2024, or the Merger Agreement, with Aventis Inc., a Pennsylvania corporation, or the Acquirer, and a wholly-owned subsidiary of Sanofi S.A., or Sanofi, and Art Acquisition Sub, Inc., a Delaware corporation, or the Merger Sub, and a wholly-owned subsidiary of Acquirer, along with a Separation and Distribution Agreement, dated as of January 22, 2024, by and among the Former Parent, the Company and Acquirer. The Merger Agreement provided for the acquisition by Acquirer of the Former Parent, or the Merger, to be accomplished through the merger of Merger Sub with and into the Former Parent with the Former Parent continuing as the surviving entity.

On May 29, 2024, the Former Parent completed a distribution to holders of its shares of common stock of 92% of the issued and outstanding shares of common stock of the Company, or the Distribution. On May 30, 2024, the Former Parent completed the Merger, pursuant to which (i) all assets and liabilities primarily related to INBRX-101, or the 101 Business, were transferred to the Acquirer, a wholly-owned subsidiary of Sanofi; and (ii) by way of a series of internal restructuring transactions, or the Separation, the Company acquired the assets and liabilities and corporate infrastructure associated with its ongoing programs, INBRX-106 and ozekibart (INBRX-109), and its discovery pipeline, as well as the remaining close-out obligations related to its previously terminated program, INBRX-105. Upon the closing of the Merger, the Company became a stand-alone, publicly traded company.

In connection with the foregoing transactions, each Former Parent stockholder received: (i) $30.00 per share in cash, (ii) one contingent value right per share, representing the right to receive a contingent payment of $5.00 in cash upon the achievement of a regulatory milestone, and (iii) one SEC-registered, publicly listed, share of Inhibrx for every

four shares of the Former Parent's common stock held. The Acquirer retained an equity interest in the Company of 8% upon the Distribution.

The Acquirer paid transaction consideration of $1.9 billion, including the $30.00 per share consideration and the assumption of the Company's third-party debt. See Note 3 for further discussion on the extinguishment of the Company's Amended 2020 Loans with Oxford (as defined below). In addition, the Acquirer assumed all assets and liabilities under contracts primarily related to INBRX-101 upon close of the Merger. The Acquirer also reimbursed the Company or paid on behalf of the Company $68.0 million in transaction costs. The Acquirer may pay an additional $300.0 million in consideration under the contingent value rights issued upon the achievement of a regulatory milestone.

Notwithstanding the legal form of the spin-off, the Separation and Distribution is being treated as a reverse spin-off for financial accounting and reporting purposes in accordance with *ASC 505-60, Spinoffs and Reverse Spinoffs* because (i) a wholly-owned subsidiary of the Acquirer merged with and into the Former Parent immediately following the Distribution; (ii) no senior management of the Former Parent were retained by the Former Parent following the Distribution; and (iii) the size of the Company's operations relative to the 101 Business. As a reverse spin-off, the Company considers Inhibrx as the accounting spinnor of the Former Parent, and the accounting successor to the Former Parent. Therefore, for periods prior to the spin-off, the Company's financial statements are the historical financial statements of the Former Parent. For such periods, descriptions of historical business activities are presented as if the spin-off had already occurred, and the Former Parent's activities related to such assets and liabilities had been performed by the Company. In addition, for all periods prior to the spin-off, all outstanding shares referenced in these financial statements are those shares outstanding of the Former Parent at each respective date, unless otherwise indicated as adjusted for the distribution ratio. Following the spin-off, all outstanding shares referenced are those of the Company, which, as discussed above, were issued on a four-to-one ratio of the Former Parent's outstanding shares.

The Company evaluated the sale of the 101 Business in accordance with *ASC 205-20, Discontinued Operation*s, and determined that the Separation does not represent a strategic shift and thus does not qualify as a discontinued operation. The Company next evaluated the sale of the 101 Business in accordance with *ASC 805, Business Combinations*, and determined that the 101 Business does not meet the definition of a business, given that substantially all of the fair value of the gross assets transferred is concentrated in one asset. The Company then evaluated the transaction under *ASC 845, Nonmonetary Transactions*, which contains guidance on the accounting for the distribution of nonmonetary assets to stockholders of an entity in a spin-off. In accordance with this guidance, the disposal of the 101 Business has been accounted for as a dividend-in-kind, with a gain recognized for the difference between the fair value and carrying value of the disposed assets.

The Company recorded a gain on the transaction of $2.0 billion during the year ended December 31, 2024, which consists of the following components (in thousands):

	YEAR ENDED DECEMBER 31, 2024
Merger consideration for common stock, warrants, and stock options	$ 1,727,687
Book value of Amended 2020 Loans assumed by Acquirer	211,315
Book value of net assets and liabilities related to INBRX-101 assumed by Acquirer	14,496
Transaction costs paid by Acquirer	68,000
Total gain recognized	$ 2,021,498

The gain related to the Merger consideration payable to shareholders of $1.7 billion was recorded, net of consideration allocated to the shares issued to Acquirer, through a reduction to retained earnings of $1.2 billion, representing the amount of retained earnings available at the closing of the Merger, with the remaining amount of $563.8 million recorded through additional paid-in capital.

Liquidity

As of December 31, 2024, the Company had an accumulated deficit of $106.1 million and cash and cash equivalents of $152.6 million. From its inception and through December 31, 2024, the Company has devoted substantially all of its efforts to therapeutic drug discovery and development, conducting preclinical studies and clinical trials, enabling manufacturing activities in support of its therapeutic candidates, pre-commercialization activities, organizing and staffing the Company, establishing its intellectual property portfolio and raising capital to support and expand these activities.

The Company believes that its existing cash and cash equivalents will be sufficient to fund the Company's operations for at least 12 months from the date these consolidated financial statements are issued. The Company plans to finance its future cash needs through equity offerings, debt financings or other capital sources, including potential collaborations, licenses, strategic transactions and other similar arrangements.

If the Company does raise additional capital through public or private equity or convertible debt offerings, the ownership interests of its existing stockholders will be diluted, and the terms of those securities may include liquidation or other preferences that adversely affect its stockholders' rights. If the Company raises capital through additional debt financings, it may be subject to covenants limiting or restricting its ability to take specific actions, such as incurring additional debt or making certain capital expenditures. To the extent that the Company raises additional capital through strategic licensing, collaboration or other similar agreements, it may have to relinquish valuable rights to its therapeutic candidates, future revenue streams or research programs at an earlier stage of development or on less favorable terms than it would otherwise choose, or to grant licenses on terms that may not be favorable to the Company. There can be no assurance as to the availability or terms upon which such financing and capital might be available in the future. If the Company is unable to secure adequate additional funding, it will need to reevaluate its operating plan and may be forced to make reductions in spending, extend payment terms with suppliers, liquidate assets where possible, delay, scale back or eliminate some or all of its development programs, or relinquish rights to its technology on less favorable terms than it would otherwise choose. These actions could materially impact its business, financial condition, results of operations and prospects.

The rules and regulations of the SEC or any other regulatory agencies may restrict the Company's ability to conduct certain types of financing activities, or may affect the timing of and amounts it can raise by undertaking such activities.

Use of Estimates

The preparation of these consolidated financial statements in conformity with GAAP requires the Company to make estimates and judgments that affect the reported amounts of assets, liabilities, revenue and expense and the disclosure of contingent assets and liabilities in the Company's financial statements and accompanying notes. The Company's most significant estimates relate to evaluation of whether revenue recognition criteria have been met, accounting for development work and preclinical studies and clinical trials, determining the assumptions used in measuring stock-based compensation, and the incremental borrowing rate estimated in relation to the Company's operating lease. The Company bases its estimates on historical experience, known trends and other market-specific or other relevant factors that it believes to be reasonable under the circumstances. Estimates are periodically reviewed in light of changes in circumstances, facts and experience. Changes in estimates are recorded in the period in which they become known. The Company's actual results may differ from these estimates under different assumptions or conditions.

Cash and Cash Equivalents

Cash and cash equivalents are comprised of cash held in financial institutions including readily available checking, overnight sweep, and money market accounts.

Concentrations of Credit Risk

Financial instruments that subject the Company to significant concentrations of credit risk consist primarily of cash and cash equivalents. The Company maintains deposits in federally insured financial institutions in excess of federally insured limits by the Federal Deposit Insurance Corporation, or the FDIC, of up to $250,000. The Company's cash management and investment policy limits investment instruments to investment-grade securities

with the objective to preserve capital and to maintain liquidity until the funds can be used in operations. The Company has not experienced any losses in such accounts and believes it is not exposed to significant risk on its cash balances due to the financial condition of the depository institutions in which those deposits are held.

The Company continually evaluates its accounts receivable for all outstanding third-party balances to determine the potential exposure to a concentration of credit risk. The Company's major third-party contracting parties, some of which account for significant balances in both accounts receivable and revenue, are generally large, credit-worthy biotechnology companies and government bodies. The Company assesses the collectability of accounts receivable through a review of its current aging, as well as an analysis of its historical collection rate, general economic conditions, and credit status of these third parties. As of December 31, 2024 and December 31, 2023, all outstanding accounts receivable were deemed to be fully collectible, and therefore, no allowance for credit losses was recorded.

Dividends

As of December 31, 2024, the Company has never declared or paid any dividends on its common stock.

Any future determination to pay dividends on the Company's common stock will be at the discretion of the Company's board of directors and will depend upon, among other factors, the results of operations, financial condition, capital requirements, contract restrictions, business prospects and other factors the Company's board of directors may deem relevant.

Property and Equipment, Net

Property and equipment are stated at cost less accumulated depreciation. Depreciation is provided on a straight-line basis over the estimated useful lives of the assets. The Company estimates useful lives as follows:

- laboratory and office equipment: three to five years;
- furniture, fixtures and other: five years; and
- computer software: three years.

Amortization of leasehold improvements is provided on a straight-line basis over the shorter of their estimated useful lives or the lease term. The costs of additions and betterments are capitalized, and repairs and maintenance costs are expensed in the periods incurred.

Impairment of Long-Lived Assets

The Company reviews long-lived assets for impairment whenever events or circumstances indicate that the carrying amount of an asset may not be recoverable. An impairment loss is recognized when estimated undiscounted future cash flows expected to result from the use of the asset and its eventual disposition are less than its carrying amount. If such assets are considered impaired, the amount of the impairment loss recognized is measured as the amount by which the carrying value of the asset exceeds the fair value of the asset, fair value being determined based upon future cash flows or appraised values, depending on the nature of the asset. The Company recognized no impairment losses during any of the periods presented within its consolidated financial statements.

Leases

The Company determines whether a contract is, or contains, a lease at inception based on the unique facts and circumstances present in the contract. The Company evaluates classification of leases as either operating or finance at commencement and, as necessary, at modification.

At lease commencement for leases with terms greater than 12 months, the Company records a lease liability determined as the present value of future lease payments over the expected lease term. The Company calculates the present value of future lease payments using an estimated incremental borrowing rate that the Company would have to pay to borrow equivalent funds on a collateralized basis at the lease commencement date. The Company also records an operating right-of-use asset based on the liability as adjusted for any lease incentives or prepaids. The lease term at the commencement date is determined by considering whether renewal options and termination options are reasonably assured of exercise.

After lease commencement, assumptions made by the Company at the commencement date are re-evaluated upon the occurrence of certain events, including a lease modification. The Company evaluates any change to an existing lease to determine if it constitutes a separate contract or a single contract with the existing lease. For modifications treated as a single contract, the Company reassesses the lease classification, remeasures the related lease liability using an updated discount rate as of the effective date of the modification, and recognizes the amount of the remeasurement of the lease liability for the modified lease as an adjustment to the corresponding right-of-use asset under the lease modification guidance pursuant to *ASC 842, Leases*. If a lease continues to exist, the lease modification is determined to be a separate contract when the modification grants the lessee an additional right-of-use asset that is not included in the original lease and the lease payments increase commensurate with the standalone price for the additional right-of-use asset. When a lease modification results in a separate contract, it is accounted for in the same manner as a new lease.

The Company accounts for lease and non-lease components in its lease agreements as a single lease component in determining lease assets and liabilities. In addition, the Company does not recognize the right-of-use assets and liabilities for leases with lease terms of twelve months or less, instead recognizing lease payments as operating expenses on a straight-line basis over the lease term.

Investment in Phylaxis

The Company uses the equity method of accounting for equity investments in companies if the investment provides the ability to exercise significant influence, but not control, over operating and financial policies of the investee. As discussed in Note 6, the Company received an equity investment in the form of a 10% equity interest as consideration in a series of agreements with Phylaxis (as defined below), which was later increased to 15% in the fourth quarter of 2023 following the achievement of a milestone. This equity interest is accounted for as an equity method investment and the Company's proportionate share of the net income or loss of Phylaxis is included as loss in equity method investment in the consolidated statement of operations. Judgment regarding the level of influence over each equity method investment includes considering key factors such as the Company's ownership interest, representation on the board of directors, legal form of the investee (e.g. limited liability corporation), participation in policy-making decisions, and material purchase and sale transactions.

The investment had been reduced to zero prior to the beginning of 2021 as a result of the allocation of the Company's share of prior losses of the investee. Following the Company's increase in equity interest of 5% in the fourth quarter of 2023, the Company established an additional equity method investment and subsequently recorded its proportionate loss as loss in equity method investment in the consolidated statement of operations. Accordingly, the Company's investment in Phylaxis as of December 31, 2024 and December 31, 2023 is zero.

Fair Value of Financial Instruments

The Company's financial instruments held during the periods presented consisted principally of accounts receivable, investments in debt securities, accounts payable, accrued expense, long-term debt, and warrants. The carrying amounts of financial instruments such as accounts receivable, accounts payable, accrued expense, and investments in debt securities classified as cash equivalents approximated their related fair values due to the short-term nature of these instruments. The carrying value of the Company's debt approximated fair value due to its interest being reflective of current market rates for debt with similar terms and conditions. The Company's warrants are equity-classified and carried at the instruments' fair value upon classification into equity.

Fair Value Measurements

The Company determines the fair value measurements of applicable assets and liabilities based on a three-tier fair value hierarchy established by accounting guidance and prioritizes the inputs used in measuring fair value. These tiers include:

- Level 1 - Quoted prices in active markets for identical assets or liabilities.
- Level 2 - Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

- Level 3 - Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

In certain cases, the inputs used to measure fair value may fall into different levels of the fair value hierarchy. In such cases, the level in the fair value hierarchy within which the fair value measurement in its entirety falls has been determined based on the lowest level input that is significant to the fair value measurement in its entirety. The Company's assessment of the significance of a particular input to the fair value measurement in its entirety requires judgment and considers factors specific to the asset or liability.

As of December 31, 2024 and December 31, 2023, the Company held $149.0 million and $264.4 million, respectively, of money market mutual funds or equivalents, which are classified as Level 1 in the fair value hierarchy. During the year ended December 31, 2023, the Company's investments in debt securities consisted of U.S. Treasury Bills, which are classified as Level 1 in the fair value hierarchy. Due to the short-term nature of these securities which are classified as cash equivalents, the amortized value approximated fair value and the Company did not remeasure these instruments at fair value. As of December 31, 2024 and December 31, 2023, the Company held no investments in debt securities. The Company's long-term outstanding debt as of December 31, 2023 is classified as Level 2 in the fair value hierarchy. As of December 31, 2024 and December 31, 2023, the Company had no financial instruments measured at fair value on a recurring basis.

Deferred Financing Costs and Other Debt-Related Costs

Deferred financing costs are capitalized, recorded as an offset to the Company's debt balances and amortized as interest expense over the term of the associated debt instrument using the effective interest method, pursuant to *ASC Topic 835-30, Imputation of Interest*. If the maturity of the debt is accelerated as a result of default or early debt repayment, the amortization would then be accelerated. Amounts paid related to debt financing activities are presented on the consolidated balance sheet as a direct deduction from the debt liability.

Financial Instruments with Characteristics of Both Liabilities and Equity

The Company accounts for issued warrants either as a liability or equity in accordance with *ASC 480-10, Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity*, or ASC 480-10, and *ASC 815-40, Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock*, or ASC 815-40. Under ASC 480-10, warrants are considered a liability if they are mandatorily redeemable and they require settlement in cash, other assets, or a variable number of shares. If warrants do not meet liability classification under ASC 480-10, the Company considers the requirements of ASC 815-40 to determine whether the warrants should be classified as a liability or as equity. Under ASC 815-40, contracts that may require settlement for cash are liabilities, regardless of the probability of the occurrence of the triggering event. Liability-classified warrants are measured at fair value on the issuance date and at the end of each reporting period. Any change in the fair value of the warrants after the issuance date is recorded in other expense, net in the consolidated statements of operations as a gain or loss. If warrants do not require liability classification under ASC 815-40, in order to conclude warrants should be classified as equity, the Company assesses whether the warrants are indexed to its common stock and whether the warrants are classified as equity under ASC 815-40 or under another applicable GAAP standard. Equity-classified warrants are accounted for at fair value on the issuance date with no changes in fair value recognized after the issuance date. The Company's outstanding warrants do not meet the requirements for liability classification under ASC-480-10 or ASC-815-40. Therefore, the Company's outstanding warrants are classified as equity as of and for the years ended December 31, 2024 and December 31, 2023.

Revenue Recognition

The Company has historically generated revenue from its license and collaboration agreements with partners, as well as from grants from government agencies and private not-for-profit organizations.

Collaborative Research, Development, and License Agreements

The Company enters into collaborative agreements with partners which may include the transfer of licenses, options to license, and the performance of research and development activities. The terms associated with these agreements may include one or more of the following (1) license fees; (2) nonrefundable up-front fees; (3) payments for reimbursement of research costs; (4) payments associated with achieving specific development, regulatory, or

commercial milestones; and (5) royalties based on specified percentages of net product sales, if any. Payments received from customers are included in deferred revenue, allocated between current and non-current on the consolidated balance sheet, until all revenue recognition criteria are met.

Typically, license fees, non-refundable upfront fees, and funding of research activities are considered fixed, while milestone payments, including option exercise fees, are identified as variable consideration, which is constrained and excluded from the transaction price. The Company will recognize revenue for sales-based royalty if and when a subsequent sale occurs.

The Company applies significant judgment when making estimates and assumptions under these agreements, including evaluating whether contractual obligations represent distinct performance obligations, including the assessment of whether options represent material rights, determining whether there are observable standalone prices and allocating transaction price to performance obligations within a contract, assessing whether any licenses are functional or symbolic, determining when performance obligations have been met, and assessing the recognition of variable consideration. The Company evaluates each performance obligation to determine if it can be satisfied and recognized as revenue at a point in time or over time. Typically, performance obligations consisting of a transfer of a license or the achievement of milestones are recognized at a point in time upon the transfer, while performance obligations consisting of research activities are recognized over time using an input method which is representative of the Company's efforts to fulfill the performance obligation, based on costs incurred with third-parties or internal labor hours performed.

Accrued Research and Development and Clinical Trial Costs

Research and development costs are expensed as incurred based on estimates of the period in which services and efforts are expended, and include the cost of compensation and related expenses, as well as expenses for third parties who conduct research and development on the Company's behalf, pursuant to development and consulting agreements in place. The Company's preclinical studies and clinical trials are performed internally, by third party contract research organizations, or CROs, and/or clinical investigators. The Company also engages with contract development and manufacturing organizations, or CDMOs, for clinical supplies and manufacturing scale-up activities related to its therapeutic candidates. Invoicing from these third parties may be monthly based upon services performed or based upon milestones achieved. The Company accrues these expenses based upon estimates determined by reviewing cost information provided by CROs and CDMOs, other third-party vendors and internal clinical personnel, and contractual arrangements with CROs and CDMOs and the scope of work to be performed. Costs incurred related to the Company's purchases of in-process research and development for early-stage products or products that are not commercially viable and ready for use, or have no alternative future use, are charged to expense in the period incurred. Costs incurred related to the licensing of products that have not yet received marketing approval to be marketed, or that are not commercially viable and ready for use, or have no alternative future use, are charged to expense in the period incurred.

Income Taxes

Income taxes are accounted for under the asset and liability method. Deferred income taxes are recorded for temporary differences between financial statement carrying amounts and the tax basis of assets and liabilities. Deferred tax assets and liabilities reflect the tax rates expected to be in effect for the years in which the differences are expected to reverse. A valuation allowance is provided if it is more likely than not that some or all of the deferred tax assets will not be realized.

The Company also follows the provisions of accounting for uncertainty in income taxes which prescribes a model for the recognition and measurement of a tax position taken or expected to be taken in a tax return, and provides guidance on derecognition, classification, interest and penalties, disclosure and transition.

The utilization of unused federal and state net operating losses, or NOLs, and research tax credit carryforwards to offset future taxable income may be subject to an annual limitation as a result of ownership changes that have occurred previously or may occur in the future. Under Sections 382 and 383 of the Internal Revenue Code, as amended, or IRC, a corporation that undergoes an "ownership change" may be subject to limitations on its ability to utilize its pre-change NOLs and other tax attributes otherwise available to offset future taxable income and/or tax liability. An ownership change is defined as a cumulative change of 50 percentage points or more in the ownership

positions of certain stockholders or groups of stockholders during a rolling three-year period. It is possible that the Company may incur ownership changes in the future. If an ownership change occurs, the Company's ability to use its NOL or tax credit carryforwards may be restricted, which could require the Company to pay federal or state income taxes earlier than would be required if such limitations were not in effect.

Earnings (Loss) Per Share

Basic earnings (loss) per share is computed by dividing net income (loss) by the weighted average number of common stock outstanding during the same period. Diluted earnings (loss) per share is computed by dividing net income (loss) by the weighted average number of shares of common stock and potentially dilutive common shares outstanding during the same period. The Company excludes common stock equivalents from the calculation of diluted net earnings (loss) per share when the effect is anti-dilutive.

The weighted average number of shares of common stock used in the basic and diluted net income (loss) per common stock calculations includes the weighted-average pre-funded warrants outstanding during the period as they are exercisable at any time for nominal cash consideration.

During the year ended December 31, 2024, outstanding shares during the period consist both of shares of the Former Parent and of the Company. For purposes of computing earnings (loss) per share only, for all periods presented in its consolidated statements of operations, the Company adjusted all outstanding shares of the Former Parent, including potentially dilutive securities, by the four-to-one distribution ratio used in the Distribution.

In periods in which the Company has net income, the Company applies the treasury stock method to determine the dilutive effect of potentially dilutive securities. Potentially dilutive securities included in the diluted earnings per share are as follows (in thousands):

	YEAR ENDED DECEMBER 31, 2024
Outstanding stock options	182
Total	182

In periods in which the Company has a net loss, basic loss per share and diluted loss per share are identical since the effect of potentially dilutive common shares is anti-dilutive and therefore excluded. Accordingly, for the year ended December 31, 2023, there is no difference in the number of shares used to calculate basic and diluted shares outstanding.

Potentially dilutive securities not included in the calculation of diluted net loss per share, as weighted based on the period outstanding during the year, are as follows (in thousands):

	YEAR ENDED DECEMBER 31, 2023
Outstanding stock options	1,584
Warrants to purchase common stock	12
Total	1,596

Fair Value of Stock-Based Awards

The Company recognizes compensation costs related to stock options based on the estimated fair value of the awards on the date of grant. The Company estimates the grant date fair value, and the resulting stock-based compensation expense, using the Black-Scholes option pricing model. The grant date fair value of the stock-based awards is generally recognized on a straight-line basis over the requisite service period, which is generally the vesting period of the respective awards. The Company recognizes forfeitures as they occur. The Company determines the assumptions used in the option pricing model in the following manner:

Risk-Free Interest Rate—For the determination of the risk-free interest rates, the Company utilizes the U.S. Treasury yield curve for instruments in effect at the time of measurement with a term commensurate with the expected term assumption.

Expected Volatility—Due to the Company's limited historical stock price volatility data indicative of the expected future volatility, the Company based its estimate of expected volatility on the estimated and expected volatilities of a guideline group of publicly traded companies. For these analyses, the Company selected companies with comparable characteristics including enterprise value, risk profiles, 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 Company will continue to apply this process until a sufficient amount of historical information regarding the volatility of its own stock price becomes available, or until the volatility of the Company's market-traded shares best represents its expected volatility.

Expected Dividend—The expected dividend yield is assumed to be zero since the Company has never paid dividends and does not have current plans to pay any dividends on its common stock.

Expected Term—The Company estimates the expected term of its stock options granted to employees and non-employee directors using the simplified method, whereby, the expected term equals the average of the vesting term and the original contractual term of the option. The Company utilizes this method since it does not have sufficient historical exercise data to provide a reasonable basis upon which to estimate the expected term.

Other Comprehensive Income

The Company has no material components of other comprehensive loss and accordingly, net loss is equal to comprehensive loss in all periods presented.

Segment Information

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision-maker, or CODM, in making decisions regarding resource allocation and assessing performance. The Company's CODM has been identified as the Chief Executive Officer, who reviews financial results at a consolidated level only. The Company views its operations and manages its business as one operating and reportable segment as the Company has devoted substantially all of its resources to drug discovery and development activities through conducting preclinical studies and clinical trials associated with its programs, all of which aim to discover and develop biologic therapeutic candidates.

The CODM assesses performance for the biologic therapeutic segment and decides how to allocate resources based on the consolidated net income (loss) as reported on its consolidated income statement. The accounting policies of the reportable segment are the same as those described in the summary of significant accounting policies. The measure of segment assets is reported on the consolidated balance sheet as total consolidated assets. The segment depreciation expense, interest expense, interest income, and segment asset additions are consistent with consolidated amounts reported within the consolidated statement of cash flows given the Company's operations are aggregated within a single reportable segment. The total segment amount of loss on equity method investment for the segment is also consistent with the consolidated amount of loss on equity method investment reported within the consolidated statement of operations and comprehensive loss.

The Company's revenues to date under this segment have been derived from licenses with collaboration partners and grant awards, and the Company has not generated any revenue from the commercial sale of approved therapeutic products (see Note 6). As a result, the Company has incurred operating losses since its inception and expects to continue to incur significant expenses and operating losses for the foreseeable future as it advances its therapeutic candidates through all stages of development and clinical trials and, ultimately, seeks regulatory approval. The CODM uses net income (loss) and the components of operating expense to assess the Company's operating results and performance and make operating decisions regarding the allocation of resources to best support the long-term growth of the Company's overall business.

The table below summarizes the significant segment revenue and significant segment expenses which are regularly reported to and reviewed by the CODM for the purposes of making decisions regarding the allocation of resources and are reconciled to consolidated net income (loss) for the years ended December 31, 2024 and December 31, 2023 (in thousands):

	YEAR ENDED DECEMBER 31,	
	2024	2023
Segment net income (loss)		
Revenue	$ 200	$ 1,800
Research and development expense		
Personnel	72,790	47,818
Contract manufacturing	55,643	77,248
Clinical trials	47,665	42,960
Equipment, depreciation, and facility	9,693	7,401
Other research and development	17,952	16,213
General and administrative expense		
Merger-related	68,061	36
Personnel	37,649	17,762
Other general and administrative	22,195	11,583
Other income (expense)	2,019,022	(20,503)
Other segment expenses[(1)]	2	1,637
Segment and consolidated net income (loss)	$ 1,687,572	$ (241,361)

(1) Other segment expenses include provision for income taxes and loss on equity method investments.

Recent Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board, or FASB, or other standard setting bodies. The Company believes that the impact of the recently issued accounting pronouncements that are not yet effective will not have a material impact on its consolidated financial condition or results of operations upon adoption.

Adoption of New Accounting Pronouncements

In November 2023, the FASB issued Accounting Standards Update, or ASU, 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures*, which updates reportable segment disclosure requirements primarily through enhanced disclosures about significant segment expenses. The amendments are effective for fiscal years beginning after December 15, 2023, and for interim periods within fiscal years beginning after December 15, 2024. The Company adopted this standard for its 2024 annual consolidated financial statements and interim consolidated financial statements thereafter and has applied it retrospectively to all prior periods presented in the financial statements. The adoption of this ASU did not result in a material impact on its consolidated financial statements, other than the newly required disclosures included above in Note 1.

Recently Issued but Not Yet Adopted Accounting Pronouncements

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740): Improvement to Income Tax Disclosures* to enhance the transparency and decision usefulness of income tax disclosures. Two primary enhancements related to this ASU include disaggregating existing income tax disclosures relating to the effective tax rate reconciliation and income taxes paid. ASU 2023-09 is effective for annual periods beginning after December 15, 2024 on a prospective basis. Early adoption is permitted. The Company is currently evaluating the impact of this accounting standard update on the Company's consolidated financial statements and related disclosures.

In November 2024, the FASB issued ASU 2024-03, *Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses*, which requires additional disclosure about specific expense categories in the notes to financial statements. The amendments are effective for fiscal years beginning after December 15, 2026, and for interim periods within fiscal years beginning after December 15, 2027. Early adoption is permitted. The amendments should be applied either prospectively to financial statements issued for reporting periods after the effective date of this ASU or retrospectively to any or all prior periods presented in the financial statements. The Company is currently evaluating the impact of this accounting standard update on the Company's consolidated financial statements and related disclosures.

2. OTHER FINANCIAL INFORMATION

Prepaid Expense and Other Current Assets

Prepaid expense and other current assets were comprised of the following (in thousands):

	AS OF DECEMBER 31,	
	2024	**2023**
Clinical trials [1]	$ 3,544	$ 5,409
Clinical drug substance and product manufacturing [2]	1,998	9,888
Licenses	816	728
Outside research and development services [3]	642	265
Other	382	366
Prepaid expense and other current assets	$ 7,382	$ 16,656

(1) Relates primarily to the Company's prepayments to third-party CROs for management of clinical trials and prepayments for drug supply to be used in combination with the Company's therapeutics. See "Accrued Research and Development Clinical Trial Costs" in Note 1 for further discussion of the components of research and development.
(2) Relates primarily to the Company's usage of third-party CDMOs for clinical and development efforts. See "Accrued Research and Development Clinical Trial Costs" in Note 1 for further discussion of the components of research and development.
(3) Relates to the Company's usage of third parties for other research and development efforts. See "Accrued Research and Development Clinical Trial Costs" in Note 1 for further discussion of the components of research and development.

Property and Equipment, Net

Property and equipment, net were comprised of the following (in thousands):

	AS OF DECEMBER 31,	
	2024	**2023**
Machinery and equipment	$ 9,758	$ 8,480
Computer software	3,984	53
Furniture, fixtures and other	556	540
Leasehold improvements	795	441
Construction in process [1]	—	3,592
Total property and equipment	15,093	13,106
Less: accumulated depreciation and amortization	(8,893)	(6,687)
Property and equipment, net	$ 6,200	$ 6,419

(1) As of December 31, 2023, consists of renovations to the Company's office space and software not yet placed in service.

Depreciation and amortization expense for each of the years ended December 31, 2024 and December 31, 2023, and consisted of the following (in thousands):

	YEAR ENDED DECEMBER 31,	
	2024	2023
Research and development	$ 1,881	$ 992
General and administrative	404	199
Total depreciation and amortization expense	$ 2,285	$ 1,191

Accrued Expenses

Accrued expenses were comprised of the following (in thousands):

	AS OF DECEMBER 31,	
	2024	2023
Clinical trials [1]	$ 14,796	$ 9,224
Compensation expense	7,726	6,506
Clinical drug substance and product manufacturing [2]	5,642	22,805
Other outside research and development [3]	632	1,129
Professional fees	629	780
Interest expense	—	2,348
Other	465	503
Accrued expenses	$ 29,890	$ 43,295

(1) Relates primarily to the Company's usage of third-party CROs for management of clinical trials. See "Accrued Research and Development Clinical Trial Costs" in Note 1 for further discussion of the components of research and development.
(2) Relates primarily to the Company's usage of third-party CDMOs for clinical and development efforts. See "Accrued Research and Development Clinical Trial Costs" in Note 1 for further discussion of the components of research and development.
(3) Relates to the Company's usage of third parties for other research and development efforts. See "Accrued Research and Development Clinical Trial Costs" in Note 1 for further discussion of the components of research and development.

3. DEBT

2020 Loan Agreement

In July 2020, the Company entered into a loan and security agreement, or the 2020 Loan Agreement, with Oxford Finance LLC and other lenders, or collectively, Oxford. Under the original 2020 Loan Agreement and subsequent amendments between November 2020 and October 2022, or collectively, the Amended 2020 Loan Agreement, the Company received an aggregate principal amount of $200.0 million over seven tranches, or Terms A-G.

Prior to the Separation, the outstanding term loans were to mature on January 1, 2027, or the Amended Maturity Date. Under the Amended 2020 Loan Agreement, and through the Separation, the repayment schedule provided for interest-only payments through February 1, 2025, followed by 23 months of principal and interest payments. Upon the Amended Maturity Date, a final payment of 9.0% of the original principal amount would be due to Oxford. This final payment of $18.0 million was being accreted over the life of the Amended 2020 Loan Agreement using the effective interest method. The Company had the option to prepay the outstanding balance of the term loans in full prior to the Amended Maturity Date, subject to a prepayment fee ranging from 1.0% to 3.0%, depending upon the timing of the prepayment.

In connection with the Separation, the Company's outstanding debt was assumed by the Acquirer. Prior to the close of the Merger, the Company had $200.0 million in gross principal outstanding in term loans under the Amended 2020 Loan Agreement. The Acquirer assumed the outstanding debt balance in full, consisting of the $200.0 million in gross principal, the $18.0 million final payment fee, and accrued interest of $2.3 million, net of debt discounts of $9.0 million.

The Company determined the Acquirer's assumption and subsequent repayment of the outstanding debt constitutes an extinguishment of the debt as the Company has been legally released from being the primary obligor under the

liability. The Company did not make any payment upon the extinguishment of the debt and did not incur any prepayment penalties. Upon the Acquirer's assumption of the outstanding debt, the Company recorded a gain of $211.3 million, the net carrying amount of the Amended 2020 Loans upon extinguishment, within the gain related to transaction with Acquirer in its consolidated statements of operations.

Interest Expense

Prior to the Separation, interest expense was calculated using the effective interest method and was inclusive of non-cash amortization of the debt discount and accretion of the final payment. During the year ended December 31, 2024, interest expense was $13.5 million, $2.1 million of which related to non-cash amortization of the debt discount and accretion of the final payment. During the year ended December 31, 2023, interest expense was $31.8 million, $4.9 million of which related to non-cash amortization of the debt discount and accretion of the final payment.

4. STOCKHOLDERS' EQUITY

Amended and Restated Certificate of Incorporation

On May 29, 2024, upon effecting the Separation, the Company's certificate of incorporation was amended and restated to authorize 120,000,000 shares of common stock and 15,000,000 shares of preferred stock, each with a par value of $0.0001 per share.

Common Stock

Following the Distribution and as of May 29, 2024, the Company had 14,475,904 shares of common stock outstanding. The Company issued one SEC-registered, publicly listed, share of Inhibrx for every four shares of the Former Parent's common stock held, resulting in 13,316,140 shares of common stock issued to common stockholders of the Former Parent. Upon the Distribution, the Former Parent retained an equity interest in the Company of 8%, or 1,157,926 shares. The Company issued 1,838 shares of common stock to Oxford in connection with the Oxford Warrants (as defined below) in the Distribution.

Securities Purchase Agreement

In August 2023, the Company entered into a Securities Purchase Agreement, as amended, or the Purchase Agreement, with certain institutional and other accredited investors, or Purchasers, pursuant to which the Company sold and issued 3,621,314 shares of the Company's common stock for $19.35 per share and pre-funded warrants to purchase 6,714,636 shares of the Company's common stock in a private placement transaction, or the Private Placement. The purchase price of the pre-funded warrants was $19.3499 per pre-funded warrant, with an exercise price of $0.0001 per share. The pre-funded warrants were equity-classified and carried at the instruments' fair value upon issuance. During the second quarter of 2024, certain Purchasers exercised 2,747,245 pre-funded warrants on a cashless basis for a net of 2,746,454 shares of the Former Parent's common stock.

In connection with the Merger Agreement, the Former Parent entered into an Agreement Relating to the Pre-Funded Warrant to Purchase Common Stock and Securities Purchase Agreement, with each holder of the pre-funded warrants purchased in the Private Placement so that on the date of the Distribution, any remaining pre-funded warrants of the Former Parent not already exercised became exercisable for an equivalent number of shares of the Company's common stock at an exercise price of $0.0001 per share, pursuant to certain beneficial ownership limitations. The Company accounted for this amendment as a modification to the original Purchase Agreement.

As part of the Separation and Distribution, each holder of outstanding pre-funded warrants received (i) $30.00 per pre-funded warrant in cash, less the applicable exercise price per share, (ii) one contingent value right per share, representing the right to receive a contingent payment of $5.00 in cash upon the achievement of a regulatory milestone, and (iii) one pre-funded warrant of Inhibrx for every four of the Former Parent's pre-funded warrants held. Following the Separation and Distribution and as of December 31, 2024, pre-funded warrants to purchase 991,849 shares of the Company's common stock are outstanding at an exercise price of $0.0001 per share. The pre-funded warrants are exercisable upon issuance pursuant to certain beneficial ownership limitations as defined in the Purchase Agreement, as amended, and will expire when exercised in full.

Warrants Issued in Connection with Amended 2020 Loan Agreement

In connection with the Amended 2020 Loan Agreement, the Company issued equity-classified warrants to Oxford, or the Oxford Warrants in two tranches: (i) 7,354 warrants with an exercise price of $17.00 and (ii) 40,000 warrants with an exercise price of $45.00. As part of the Separation and Distribution, each holder of eligible outstanding warrants received (i) $30.00 per warrant in cash, less the applicable exercise price per share (ii) one contingent value right per share, representing the right to receive a contingent payment of $5.00 in cash upon the achievement of a regulatory milestone, and (iii) one SEC-registered, publicly listed, share of Inhibrx for every four of the Former Parent's warrants held. All outstanding warrants with an exercise price which exceeded the total consideration of $35.00 were canceled upon the Merger for no consideration.

Following the Separation and as of December 31, 2024, no Oxford Warrants were outstanding.

Common Stock Reserved for Future Issuance

Common stock reserved for future issuance as of December 31, 2024 for the Company and December 31, 2023 for the Former Parent consisted of the following (in thousands):

	AS OF DECEMBER 31,	
	2024	**2023**
Options to purchase common stock issued and outstanding	3,660	6,494
Shares available for future equity grants	340	533
Pre-funded warrants issued and outstanding	992	6,715
Warrants issued and outstanding	—	47
Total common stock reserved for future issuance	4,992	13,789

5. EQUITY COMPENSATION PLAN

2017 Plan

The Company's share-based compensation plan, the Amended and Restated 2017 Employee, Director and Consultant Equity Incentive Plan, or the 2017 Plan, provided for the issuance of incentive stock options, restricted and unrestricted stock awards, and other stock-based awards. The 2017 Plan was terminated in connection with the Merger.

Stock Option Activity

The Company recognized compensation costs related to stock-based awards, including stock options, based on the estimated fair value of the awards on the date of grant. The Company granted options with an exercise price equal to the fair market value of the Company's stock on the date of the option grant. The options were subject to four-year vesting with a one-year cliff and had a contractual term of 10 years.

A summary of the Company's stock option activity under its 2017 Plan for the year ended December 31, 2024 is as follows (in thousands, except for per share data):

	Number of Shares	Weighted Average Exercise Price
Outstanding as of December 31, 2023	6,494	$ 23.22
Exercised	(3,449)	$ 21.11
Forfeited	(9)	$ 32.03
Settled in connection with the Merger	(2,884)	$ 24.75
Canceled in connection with the Merger	(152)	$ 41.56
Outstanding as of December 31, 2024	—	
Vested and exercisable as of December 31, 2024	—	

The aggregate intrinsic value of stock options exercised during the years ended December 31, 2024 and December 31, 2023 was $65.3 million and $2.1 million, respectively. Aggregate intrinsic value of stock options exercised and outstanding is calculated using the fair value of common stock on the date of exercise and as of December 31, 2024, respectively. The total fair value of stock options vested during the years ended December 31, 2024 and December 31, 2023 was $42.5 million and $24.9 million, respectively.

Settlement of Stock Options Upon Merger

All outstanding options with an exercise price less than or equal to the total consideration of $35.00 vested immediately upon the Merger and were settled for the consideration of: (i) $30.00 per share in cash, less the applicable exercise price of their stock option and (ii) one contingent value right per share, representing the right to receive a contingent payment of $5.00 in cash upon the achievement of a regulatory milestone. In connection with the acceleration of the eligible stock options, the Company recognized $39.3 million in stock compensation expense.

All outstanding options with an exercise price which exceeded the total consideration of $35.00 were canceled upon the Merger for no consideration. In connection with the cancellation of all unvested options with an exercise price above $35.00, the Company recognized all remaining stock compensation expense of $1.8 million.

Stock-Based Compensation Expense

Stock options are valued using the Black-Scholes Merton option pricing model on the date of grant. This option pricing model involves a number of estimates, including the expected lives of the stock options, the Company's anticipated stock volatility, and interest rates. Stock-based compensation expense was recognized using the straight-line method over the vesting period.

The weighted-average assumptions used by the Company to estimate the fair value of stock option grants using the Black-Scholes option pricing model, as well as the resulting weighted-average fair value for the year ended December 31, 2023 were as follows.

	YEAR ENDED DECEMBER 31, 2023	
Risk-free interest rate	3.77	%
Expected volatility	84.31	%
Expected dividend yield	—	%
Expected term	6.08	
Weighted average fair value	$ 16.88	

See Note 1 for further discussion in how the Company determines the assumptions used in the option pricing model.

Stock-based compensation expense for stock options under the 2017 Plan consisted of the following (in thousands):

	YEAR ENDED DECEMBER 31,	
	2024	2023
Research and development	$ 32,809	$ 16,630
General and administrative	18,725	8,216
Total stock-based compensation expense	$ 51,534	$ 24,846

As of December 31, 2024, the Company had no remaining unrecognized stock-based compensation expense related to its stock options under the 2017 Plan following the termination of the plan subsequent to the Merger.

2024 Plan

In connection with the Separation, the Company adopted the 2024 Omnibus Incentive Plan, or the 2024 Plan, which provides for the issuance of incentive stock options, restricted and unrestricted stock awards, and other stock-based awards. As of December 31, 2024, an aggregate of 4.0 million shares of common stock were authorized for issuance under the 2024 Plan, of which 0.3 million remained available for issuance. There was no activity under the 2024 Plan during the year ended December 31, 2023.

Stock Option Activity

The Company recognizes compensation costs related to stock-based awards, including stock options, based on the estimated fair value of the awards on the date of grant. The Company grants options with an exercise price equal to the fair market value of the Company's stock on the date of the option grant. All options granted to employees are subject to four-year vesting with a one-year cliff. All options granted to non-employee directors are subject to a one-year vesting term. All options have a contractual term of 10 years.

A summary of the Company's stock option activity under its 2024 Plan for the year ended December 31, 2024 is as follows (in thousands, except for per share data and years):

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (In Years)	Aggregate Intrinsic Value
Outstanding as of December 31, 2023	—			
Granted	3,700	$ 15.84		
Forfeited	(40)	$ 15.86		
Outstanding as of December 31, 2024	3,660	$ 15.84	9.4	$ 46
Vested and exercisable as of December 31, 2024	—			

No stock options were exercised or vested during the year ended December 31, 2024. The Company expects all outstanding stock options to vest.

Stock-Based Compensation Expense

Stock options are valued using the Black-Scholes Merton option pricing model on the date of grant. This option pricing model involves a number of estimates, including the expected lives of the stock options, the Company's anticipated stock volatility, and interest rates. Stock-based compensation expense is recognized using the straight-line method over the vesting period.

The weighted-average assumptions used by the Company to estimate the fair value of stock option grants using the Black-Scholes option pricing model, as well as the resulting weighted-average fair value, for the year ended December 31, 2024 were as follows:

	YEAR ENDED DECEMBER 31, 2024
Risk-free interest rate	4.56 %
Expected volatility	86.32 %
Expected dividend yield	— %
Expected term (in years)	6.06
Weighted average fair value	$ 11.89

See Note 1 for further discussion in how the Company determines the assumptions used in the option pricing model.

Stock-based compensation expense for stock options under the 2024 Plan consisted of the following (in thousands):

	YEAR ENDED DECEMBER 31, 2024
Research and development	$ 4,066
General and administrative	2,918
Total stock-based compensation expense	$ 6,984

As of December 31, 2024, the Company had $36.5 million of total unrecognized stock-based compensation expense related to its stock options under the 2024 Plan, which is expected to be recognized over a weighted-average period of 3.4 years.

6. LICENSE REVENUE

The following table summarizes the total revenue recorded in the Company's consolidated statements of operations (in thousands):

	YEAR ENDED DECEMBER 31,	
	2024	2023
License fee revenue		
Regeneron Pharmaceuticals, Inc.	$ 200	$ —
Phylaxis BioScience, LLC	—	1,634
Other	—	166
Total license fee revenue	$ 200	$ 1,800

License and Collaboration Agreements

Regeneron

In June 2020, the Company entered into an Option and License Agreement with bluebird bio, Inc., or bluebird, pursuant to which the Company granted to bluebird exclusive worldwide rights to develop binders and cell therapy products containing single domain antibodies, or sdAbs, directed to specified targets, consisting of two initial programs and up to an additional 8 programs. The Company retained all rights to the specific sdAbs outside of the cell therapy field. In November 2021, this agreement was assigned to 2seventy bio, Inc., or 2seventy, in connection with bluebird's internal restructuring and subsequent spin-out of 2seventy, and subsequently in April 2024, this agreement, or the 2020 Regeneron Agreement, was assigned to Regeneron Pharmaceuticals, Inc., or Regeneron, in connection with the divestiture of 2seventy's oncology and autoimmune pipeline to Regeneron.

In June 2022, 2seventy selected a third program and paid a non-refundable upfront option fee in exchange for a development license and an option in which Regeneron may acquire an exclusive license with respect to all binders

and cell therapy products developed under this agreement, which entitles the Company to additional fees upon exercise of the option. In connection with each program for which Regeneron exercises its option, Regeneron will be required to pay the Company a one-time, non-refundable, non-creditable fee in the low-single-digit millions. The Company is also entitled to receive certain developmental milestone payments of up to an aggregate of $51.5 million per therapeutic, as well as percentage tiered royalties on future product sales with rates in the mid-single digits. Due to the uncertainty in the achievement of the developmental milestones and future sales, the variable consideration associated with the future milestone payments has been fully constrained (excluded) from the transaction price until such time that the Company concludes that it is probable that a significant reversal of previously recognized revenue will not occur. These estimates will be re-assessed at each reporting period.

In May 2024, pursuant to the option extension terms in the 2020 Regeneron Agreement, Regeneron requested to extend the option term for its third program by an additional six months in exchange for an option extension fee of $0.1 million. The Company recognized the $0.1 million of revenue related to this extension at the point in time in which the extension was granted. In November 2024, Regeneron requested a second extension of the option term for an additional six months in exchange for an option extension fee of $0.1 million. The Company recognized the $0.1 million of revenue related to this extension at the point in time in which the extension was granted. The $0.2 million related to the option extensions is recorded as accounts receivable in the Company's consolidated balance sheets as of December 31, 2024.

During the year ended December 31, 2024, the Company recognized $0.2 million of revenue related to this agreement. The Company did not recognize any revenue under this agreement during the year ended December 31, 2023.

Phylaxis Agreements

In July 2020, the Company entered into a joint venture with Phylaxis BioScience, LLC, or Phylaxis. In connection with the joint venture, the Company entered into the following agreements: Contribution Agreement, License Agreement, Limited Liability Company Agreement, and Master Services Agreement, or collectively the Phylaxis Agreements, pursuant to which the Company licensed certain intellectual property and know-how to Phylaxis and agreed to provide services to develop certain compounds. The Company received $5.0 million in nonrefundable, upfront payments from Phylaxis under the Master Services Agreement, or the MSA. In addition, upon closing, the Company received a 10% equity interest in Phylaxis as consideration for the contribution of the license of the Company's intellectual property and know-how. Pursuant to the terms of the Phylaxis Agreements, during the fourth quarter of 2023, the Company received an additional 5% equity interest in Phylaxis following the achievement of a milestone event. Under the License Agreement, the Company is also entitled to specified development and commercialization milestone payments of up to an aggregate of $225.0 million and $175.0 million, respectively. The Company is also entitled to share in a percentage of the profits of Phylaxis under the Limited Liability Company Agreement.

The Company recognized the initial transaction price of $5.5 million, comprised of the $5.0 million in upfront payments and the fair value of the 10% equity interest of $0.5 million, over the period of performance of development services on the two compounds, which was completed during the third quarter of 2022.

During the fourth quarter of 2023, the Company transferred a second generation compound to Phylaxis, which was a milestone event under the agreements. Upon transfer, the Company received an additional 5% equity interest in Phylaxis, which has a fair value of $1.6 million. The Company recognized the fair value of the 5% equity interest as revenue and accounted for the investment under the equity method. In order to determine the fair value of the equity interest in Phylaxis upon this milestone, the Company utilized the investee's independent valuations based on recent financings from third party investors at fair market value.

During the year ended December 31, 2023 the Company recognized $1.6 million of revenue under the Phylaxis agreements. During the year ended December 31, 2024 the Company did not recognize any revenue under the Phylaxis agreements.

7. RELATED PARTY TRANSACTIONS

From time to time, the Company will enter into an agreement with a related party in the ordinary course of its business. These agreements are ratified by the Company's Board of Directors or a committee thereof pursuant to policy.

Separation and Distribution

In connection with the Separation, as discussed in Note 1, the Former Parent completed a distribution to holders of its shares of common stock of 92% of the issued and outstanding shares of common stock of the Company, or the Distribution. The Former Parent retained an equity interest in the Company of 8%, or 1,157,926 shares upon the Distribution. Accordingly, the Company identified the Acquirer as a related party following the Merger with the Former Parent.

Transition Services Agreement

In connection with the Separation, the Company also entered into the Transition Services Agreement with the Former Parent under which the Company or one of its affiliates provide the Former Parent or other Sanofi entities with certain transition services for a limited time to ensure an orderly transition following the Separation. The services that the Company agreed to provide to the Former Parent or other Sanofi entities under the Transition Services Agreement include certain finance and accounting, including payroll, tax, and procurement, information technology, legal and intellectual property, clinical study support, technical operations, regulatory, quality assurance, commercial and medical affairs, and other services. The Former Parent pays the Company for any such services received by the Former Parent or other Sanofi entities, as applicable, at agreed amounts as set forth in the Transition Services Agreement.

During the year ended December 31, 2024, the Company billed the Former Parent for $0.3 million for services performed under the Transition Services Agreement. The Company recognized this amount as other income and has received approximately $0.2 million in cash as of December 31, 2024, with the remaining balance recorded as a receivable from related parties in the Company's consolidated balance sheet.

Additionally, the Transition Services Agreement requires the Former Parent to reimburse the Company for certain severance payments made by the Company to certain Company employees whose employment was terminated as a result of the Merger. During the year ended December 31, 2024, the Company billed the Former Parent for $1.0 million of severance payments to former employees, all of which has been received as of December 31, 2024.

Pharmacovigilance Agreement

In connection with the Separation, the Company entered into a Pharmacovigilance Agreement with the Former Parent, pursuant to which the parties agreed to implement processes and procedures for sharing information as required for each party's compliance with its regulatory and pharmacovigilance responsibilities.

8. INCOME TAXES

The components of income tax expense (benefit) were as follows for the years ended December 31, 2024 and December 31, 2023, respectively (in thousands):

	YEAR ENDED DECEMBER 31,	
	2024	**2023**
Current expense:		
State	$ 2	$ 3
Total current expense	$ 2	$ 3

The provision for the years ended December 31, 2024 and December 31, 2023 was related to state income taxes.

A reconciliation of income tax expense to the amount computed by applying the statutory federal income tax rate to the loss from operations is summarized for the years ended December 31, 2024 and December 31, 2023 as follows (in thousands):

	YEAR ENDED DECEMBER 31,	
	2024	2023
Expected income tax expense (benefit) at federal statutory rate	$ 354,390	$ (50,684)
State income tax expense (benefit), net of federal benefit	10,106	(3,568)
Permanent items	6,842	1,524
R&D credits	(28,602)	(2,322)
Unrecognized tax benefits (FIN 48)	(4,651)	1,054
Elimination of deferred tax assets and liabilities upon Transaction with Acquirer	195,694	—
Non-taxable gain related to Transaction with Acquirer	(410,226)	—
336(e) election	665	—
Return to provision true-ups	—	(420)
Valuation allowance	(124,216)	54,419
Income tax expense	$ 2	$ 3

Income taxes are accounted for under the asset and liability method. Deferred income taxes are recorded for temporary differences between financial statement carrying amounts and the tax basis of assets and liabilities. Deferred tax assets and liabilities reflect the tax rates expected to be in effect for the years in which the differences are expected to reverse. A valuation allowance is provided if it is more likely than not that some or all of the deferred tax assets will not be realized.

The components of net deferred income taxes were as follows (in thousands):

	AS OF DECEMBER 31,	
	2024	2023
Deferred income tax assets		
Net operating loss carryforward	$ 4,726	$ 68,254
Research and development credits	—	12,648
Intangibles	56	3,289
Accruals	893	1,412
Stock compensation	809	8,581
Capitalized research and development costs	15,718	51,772
Operating lease liabilities	1,776	697
Other	5	10
Gross deferred tax assets	23,983	146,663
Less: Valuation allowance	(21,789)	(146,005)
Total deferred tax assets	2,194	658
Deferred income tax liabilities		
Fixed assets	(575)	(10)
Operating lease right-of-use assets	(1,619)	(648)
Total deferred tax liabilities	(2,194)	(658)
Net deferred tax assets (liabilities)	$ —	$ —

In connection with the Separation, the Former Parent retained all rights associated with the unused federal and state NOLs and research tax credit carryforwards as of the date of the transaction to offset its future taxable income. As of December 31, 2024, the Company had unused federal and state NOL carryforwards of approximately $20.3 million and $7.8 million, respectively. The federal NOL carryforwards may be carried forward indefinitely but are only available to offset up to 80% of pre-NOL taxable income each year. The state NOL carryforwards will begin to expire in 2044 if not utilized.

The utilization of NOL carryforwards to offset future taxable income may be subject to an annual limitation as a result of ownership changes that have occurred previously or may occur in the future. Under Sections 382 and 383 of the IRC, a corporation that undergoes an "ownership change" may be subject to limitations on its ability to utilize its pre-change NOLs and other tax attributes otherwise available to offset future taxable income and/or tax liability. An ownership change is defined as a cumulative change of 50 percentage points or more in the ownership positions of certain stockholders or groups of stockholders during a rolling three-year period. Following the Separation, the Company has not completed a formal study to determine if any ownership changes within the meaning of IRC Section 382 and 383 have occurred. It is possible that the Company may incur ownership changes in the future. If an ownership change has occurred, the Company's ability to use its NOL carryforwards may be restricted, which could require the Company to pay federal or state income taxes earlier than would be required if such limitations were not in effect.

The Company has established a full valuation allowance against its deferred tax assets due to uncertainties that preclude it from determining that it is more likely than not that the Company will be able to generate sufficient taxable income to realize such assets. Management assesses the available positive and negative evidence to estimate if sufficient future taxable income will be generated to utilize the existing deferred tax assets. A significant piece of objective negative evidence evaluated was the cumulative loss incurred over the three-year period ended December 31, 2024. Such objective evidence limits the ability to consider other subjective evidence such as the Company's projections for future growth. Based on this evaluation, as of December 31, 2024, a valuation allowance of $21.8 million has been recorded in order to measure only the portion of the deferred tax asset that more likely than not will be realized. The amount of the deferred tax asset considered realizable, however, could be adjusted if objective negative evidence in the form of cumulative losses is no longer present and additional weight may be given to subjective evidence, such as estimates of future taxable income during carryforward periods and the Company's projections for growth.

The Company recognizes liabilities for uncertain tax positions based on a two-step process. The first step is to evaluate the tax position for recognition by determining if the weight of available evidence indicates that it is more likely than not that the position will be sustained on audit, including resolution of related appeals or litigation processes, if any. The second step is to measure the tax benefit as the largest amount that is more than 50% likely of being realized upon settlement. While the Company believes that it has appropriate support for the positions taken on its tax returns, the Company regularly assesses the potential outcome of examinations by tax authorities in determining the adequacy of its provision for income taxes.

The following table summarizes the activity related to the Company's unrecognized tax benefits (in thousands):

	AS OF DECEMBER 31,	
	2024	2023
Beginning balance	$ 4,651	$ 3,597
Increases (decreases) related to current year tax positions	(4,651)	1,054
Ending balance	$ —	$ 4,651

As of December 31, 2024, the Company did not have any gross unrecognized tax benefits. The Company does not expect any significant increases or decreases to its unrecognized tax benefits within the next 12 months. The Company's policy is to recognize the interest expense and/or penalties related to income tax matters as a component of income tax expense. The Company had no accrual for interest or penalties on its consolidated balance sheets as of December 31, 2024 or December 31, 2023, and has not recognized interest and/or penalties in its consolidated

statements of operations for the years ended December 31, 2024 and December 31, 2023 as the unrecognized tax benefits relate to tax positions for which no cash tax liability has been reduced.

The Company is subject to income taxes in the United States and various state jurisdictions. Following the Separation, the Company's tax years from 2024 and forward are subject to examination by the United States and state tax authorities. The Company has not been, nor is it currently, under examination by the U.S. federal or any state tax authority.

9. LEASES

Operating Leases

In September 2017, the Company entered into a seven-year lease agreement as its sole location in La Jolla, California, which contains an initial base rent of approximately $0.1 million per month with 2% annual escalations. In May 2019, the Company executed an amendment to its lease agreement to expand its facilities and began occupying this space in January 2020, which contains an initial base rent of approximately $30,000 per month with 2% annual escalations. Each of these leases expires in June 2025 with an option to extend the lease an additional five years, which is not included in the right-of-use asset and lease liabilities. Payments under each of the lease agreements include base rent plus a percentage of taxes and operating expenses incurred by the lessor in connection with the ownership and management of the property, the latter of which to be determined annually.

In November 2024, the Company entered into a new lease agreement for its existing facilities, or the 2024 Lease Agreement, for the period following the expiration of its two existing leases through June 2028, with an option to extend the lease an additional three years, which is not included in the right-of-use asset and lease liabilities. This agreement did not include any additional square footage. The 2024 Lease Agreement contains initial base rent of approximately $0.2 million per month with 3% annual escalations, plus a percentage of taxes and operating expenses incurred by the lessor in connection with the ownership and management of the property, the latter of which is to be determined annually. The 2024 Lease Agreement also provided for four months of base rent abatement of $0.2 million per month for the period of October 2024 through January 2025.

The Company determined the 2024 Lease Agreement contains a lease which should be accounted for as a single modified contract with its existing lease agreements. As a result, the Company remeasured the operating lease liability, resulting in an increase to its operating lease liability and right-of-use asset of $6.3 million as of the lease's commencement date, which was determined to be the effective date of the 2024 Lease Agreement. The Company utilized an estimated incremental fully collateralized borrowing rate of 10.2% in its present value calculation as the 2024 Lease Agreement, which does not have a stated rate and did not have a readily determinable implicit rate. The estimated rate was determined using the rate of the 2025 Loan Agreement (as defined below) with Oxford entered into in January 2025.

The operating right-of-use asset and operating lease liability as of December 31, 2024 and December 31, 2023 are as follows (in thousands):

	AS OF DECEMBER 31,	
	2024	**2023**
Operating right-of-use asset	$ 7,338	$ 2,952
Operating lease liability		
Current	1,595	2,063
Non-current	6,453	1,110
Total operating lease liability	$ 8,048	$ 3,173

During the years ended December 31, 2024 and December 31, 2023, the Company recognized operating lease expense of $3.4 million and $3.7 million, respectively. During each of the years ended December 31, 2024 and December 31, 2023, the Company paid $1.7 million and $2.2 million for amounts included in the measurement of the operating lease liability in each period.

As of December 31, 2024 and December 31, 2023, the Company's operating lease had a remaining term of 3.5 and 1.5 years, respectively. The Company discounts its lease payments using its incremental borrowing rate as of the commencement of the lease. The Company has determined a weighted-average discount rate of 10.2% and 8.2% as of December 31, 2024 and December 31, 2023, respectively.

Future minimum rental commitments for the Company's operating leases reconciled to the operating lease liability are as follows (in thousands):

	AS OF DECEMBER 31, 2024
2025	$ 2,340
2026	2,855
2027	2,941
2028	1,492
Total future minimum lease payments	$ 9,628
Less: imputed interest	(1,580)
Present value of operating lease liability	8,048
Less: current portion of operating lease liability	(1,595)
Non-current portion of operating lease liability	$ 6,453

10. COMMITMENTS AND CONTINGENCIES

Litigation

The Company is not party to any material legal proceedings. From time to time, it may be involved in legal proceedings or subject to claims incident to the ordinary course of business. Regardless of the outcome, such proceedings or claims can have an adverse impact on the Company because of defense and settlement costs, diversion of resources and other factors, and there can be no assurances that favorable outcomes will be obtained.

Indemnification

In the ordinary course of business, the Company enters into agreements that may include indemnification provisions. Pursuant to such agreements, the Company may indemnify, hold harmless and defend an indemnified party for losses suffered or incurred by the indemnified party. In some cases, the indemnification obligation will continue after the termination of the agreement. The maximum potential amount of future payments the Company could be required to make under these provisions is not determinable. In addition, the Company has entered into indemnification agreements with its directors and certain officers that may require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. To date, no demands have been made upon the Company to provide indemnification under these agreements, and thus, there are no indemnification claims that the Company is aware of that could have a material effect on the Company's consolidated balance sheets, consolidated statements of operations, or consolidated statements of cash flows.

Other Commitments

Additionally, as of December 31, 2024 and December 31, 2023, Mark P. Lappe, the Company's Chief Executive Officer, Brendan P. Eckelman, the Company's Chief Scientific Officer, and Kelly D. Deck, the Company's Chief Financial Officer, and certain other members of management have agreements that provide for severance compensation in the event of termination or a change in control.

11. SUBSEQUENT EVENTS

The Company evaluated subsequent events to assess the need for potential recognition or disclosure in this report. Based upon this evaluation, it was determined that no additional subsequent events required recognition or disclosure in these consolidated financial statements, other than disclosures related to those outlined below.

Oxford Loan Agreement

On January 13, 2025, the Company entered into a Loan and Security Agreement, or the 2025 Loan Agreement, with Oxford. The 2025 Loan Agreement provides for a term loan facility of an aggregate principal amount of up to $150.0 million, or the Term Loan Facility, $100.0 million of which was funded on the consummation of the transaction, with the remaining $50.0 million to be funded upon the Company's request and at the Oxford's sole discretion. The Term Loan Facility will mature on January 1, 2030, or the Maturity Date, and bears interest at (1) 5.61% plus (2) the greater of (i) the 1-Month Term Secured Overnight Financing Right as published by the CME Group or (ii) 4.34%. The repayment schedule provides for interest-only payments through February 1, 2028, with principal payments beginning on March 1, 2028. The interest-only period is followed by 23 months of equal payments of principal plus interest.

Upon the earliest to occur of (i) the Maturity Date, (ii) the acceleration of any term loan under the Term Loan Facility, or (iii) prepayment of any term loan under the Term Loan Facility, the Company will be required to make a final payment of 9.0% of the total repaid principal amount. The Company has the option to prepay the outstanding balance of the term loan in full prior to the Maturity Date, subject to a prepayment fee ranging from 2.0% to 5.0%, depending on the timing of the prepayment. All obligations under the Oxford Loan Agreement and the other loan documents are secured by a first priority perfected lien on, and security interest in, substantially all present and future assets of the Company, subject to certain exceptions.

In connection with the initial tranche of funding under the Term Loan Facility, the Company issued warrants to Oxford, or the Term A Warrants, to purchase 140,741 shares of the Company's common stock at an exercise price of $14.21 per share. The Term A Warrants are immediately exercisable, and the exercise period will expire 10 years from the date of issuance.

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 in our reports filed pursuant to the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial and accounting officer, as appropriate, to allow timely decisions regarding required disclosure.

Our management, with the participation and supervision of our Chief Executive Officer and our Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of the end of the period covered by this Annual Report. Based on that evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that, as of the end of the period covered by this Annual Report, our disclosure controls and procedures were designed and operating effectively at the reasonable assurance level.

Inherent Limitations on Effectiveness of Controls

Our management, including our Chief Executive Officer and our Chief Financial Officer, does not expect that our disclosure controls or our internal control over financial reporting will prevent or detect all error and all fraud. A control system, no matter how well designed and operated, can provide only reasonable and not absolute assurance of achieving the desired control objectives. In reaching a reasonable level of assurance, management necessarily was required to apply its judgment in evaluating the benefits of possible controls and procedures relative to their costs. Controls can also be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the controls. In addition, the design of any system of controls is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions or deterioration in the degree of compliance with policies or procedures.

Changes in Internal Control over Financial Reporting

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

Management's Annual Report on Internal Control over Financial Reporting

Internal control over financial reporting is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act, as amended, as a process designed by, or under the supervision of, the company's principal executive and principal financial officers and effected by the Company's board of directors, management and other personnel to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with GAAP. The Company's internal control over financial reporting includes those policies and procedures that:

- pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the Company;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with GAAP, and that receipts and expenditures of the Company are being made only in accordance with authorizations of management and directors of the company; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the Company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become

inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

The Company's management assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2024. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission, or COSO, in Internal Control-Integrated Framework.

Based on our assessment, management believes that, as of December 31, 2024, the Company's internal control over financial reporting is effective based on those criteria.

Item 9B. Other Information.

During the fiscal quarter ended December 31, 2024, none of our directors or officers (as defined in Section 16 of the Securities Exchange Act of 1934, as amended) adopted or terminated any contract, instruction or written plan for the purchase or sale of our securities that was intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) or any "non-Rule 10b5-1 trading arrangement," as defined in Item 408(a) of Regulation S-K.

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

Not applicable.

Part III.

Item 10. Directors, Executive Officers and Corporate Governance.

The response to this item not otherwise set forth below is incorporated by reference from the discussion responsive thereto under the caption "Management and Corporate Governance" and, if applicable, "Delinquent Section 16(a) Reports" in our proxy statement for the 2025 annual meeting of stockholders.

Insider Trading Policy

We have adopted an insider trading policy and procedures governing the purchase, sale, and/or other dispositions of our securities by our directors, officers, employees and other covered persons that are designed to promote compliance with insider trading laws, rules and regulations, and the Nasdaq Stock Market LLC listing rules, as applicable. A copy of our Insider Trading Policy is filed as Exhibit 19 to this Annual Report. It is our policy to comply with U.S. insider trading laws and regulations, including with respect to transactions in our own securities.

Item 11. Executive Compensation.

The response to this item is incorporated by reference from the discussion responsive thereto under the captions "Executive Compensation" and "Director Compensation" in our proxy statement for the 2025 annual meeting of stockholders.

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

The response to this item is incorporated by reference from the discussion responsive thereto under the captions "Security Ownership of Certain Beneficial Owners and Management" and "Equity Compensation Plan Information" in our proxy statement for the 2025 annual meeting of stockholders.

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

The response to this item is incorporated by reference from the discussion responsive thereto under the captions "Certain Relationships and Related Party Transactions" and "Management and Corporate Governance" in our proxy statement for the 2025 annual meeting of stockholders.

Item 14. Principal Accountant Fees and Services

The response to this item is incorporated by reference from the discussion responsive thereto under the captions "Fees for Independent Registered Public Accounting Firm" and "Pre-Approval Policies and Procedures" in our proxy statement for the 2025 annual meeting of stockholders.

Part IV.

Item 15. Exhibits and Financial Statement Schedules

Exhibits

The exhibits listed in the accompanying "Index to Exhibits" below are filed or incorporated by reference as part of this Annual Report.

Financial Statement Schedules

See "Index to Consolidated Financial Statements" at Item 8 to this Annual Report. Other financial statement schedules have not been included because they are not applicable or the information is included in the financial statements or notes thereto.

Index to Exhibits

Exhibit No.	Description of Exhibit	Filed Herewith	Form	Incorporated By Reference File No.	Date Filed
2.1^	Agreement and Plan of Merger, dated as of January 22, 2024, by and among Inhibrx, Inc., Aventis Inc., and Art Acquisition Sub, Inc.		8-K	001-39452	1/23/2024
2.2^	Separation and Distribution Agreement, dated as of January 22, 2024, by and among Inhibrx, Inc., Ibex SpinCo, Inc., and Aventis Inc.		8-K	001-39452	1/23/2024
3.1	Amended & Restated Certificate of Incorporation of Inhibrx Biosciences, Inc.		8-K	001-42031	5/30/2024
3.2	Amended & Restated Bylaws of Inhibrx Biosciences, Inc.		8-K	001-42031	5/30/2024
4.1	Form of Warrant to Purchase Stock.		10	001-42031	4/25/2024
4.2	Form of Warrant to Purchase Stock by and between Inhibrx Biosciences, Inc. and entities affiliated with Oxford Finance LLC.		8-K	001-42031	1/13/2025
4.3	Description of Registered Securities	X			
10.1^	Transition Services Agreement, dated as of May 29, 2024, by and between Inhibrx Biosciences, Inc. and Inhibrx, Inc.		8-K	001-42031	5/30/2024
10.2+	Form of Indemnification Agreement.		10	001-42031	4/25/2024
10.3^	Registration Rights Agreement, dated as of May 29, 2024, by and among Inhibrx Biosciences, Inc. and the parties thereto.		8-K	001-42031	5/30/2024
10.4+	Executive Employment Agreement, effective as of May 30, 2024, by and between Inhibrx Biosciences, Inc. and Mark Lappe.		S-1	333-280127	6/11/2024
10.5+	Executive Employment Agreement, effective as of May 30, 2024, by and between Inhibrx Biosciences, Inc. and Brendan Eckelman, Ph.D.		S-1	333-280127	6/11/2024
10.6+	Executive Employment Agreement, effective as of May 30, 2024, by and between Inhibrx Biosciences, Inc. and Kelly Deck.		S-1	333-280127	6/11/2024
10.7+	2024 Omnibus Incentive Plan.		S-8	333-279840	5/30/2024
10.8+	Form of Stock Option Grant Notice under the 2024 Omnibus Incentive Plan.		8-K	001-42031	5/30/2024
10.9+	Form of Restricted Stock Unit Agreement under the 2024 Omnibus Incentive Plan.		S-8	333-279840	5/30/2024
10.10+	Nonemployee Director Compensation Policy.		10-Q	001-42031	8/13/2024

10.11	Loan and Security Agreement, dated January 13, 2025, among Inhibrx Biosciences, Inc., Oxford Finance LLC, and the other lenders party thereto.		8-K	001-42031	1/13/2025
19.1	Inhibrx Biosciences, Inc. Insider Trading Policy	X			
21.1	Subsidiaries of the Registrant.		S-1	333-280127	6/11/2024
23.1	Consent of BDO USA, P.C., independent registered public accounting firm.	X			
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) of the Securities Exchange Act, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	X			
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) of the Securities Exchange Act, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	X			
32.1*	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	X			
32.2*	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	X			
97.1	Inhibrx Biosciences, Inc. Clawback Policy	X			
101.INS	Inline XBRL Instance Document - the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document	X			
101.SCH	Inline XBRL Taxonomy Extension Schema Document	X			
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document	X			
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document	X			
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document	X			
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document	X			
104	Cover Page Interactive Data File - the cover page XBRL tags are embedded within the Inline XBRL document contained in Exhibit 101	X			

^ Certain exhibits and schedules have been omitted pursuant to Item 601(a)(5) of Regulation S-K. The Company agrees to furnish supplementally to the SEC a copy of any omitted exhibits or schedules upon request. Pursuant to Item 601(a)(6) of Regulation S-K, certain information from this exhibit have been redacted as their disclosure would constitute a clearly unwarranted invasion of personal privacy.

+ Management compensation plan or arrangement.

* This certification is deemed not filed for purposes of section 18 of the Exchange Act or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference into any filing under the Securities Act or the Exchange Act.

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, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

INHIBRX BIOSCIENCES, INC.

/s/ Mark P. Lappe

Name: Mark P. Lappe

Title: Chief Executive Officer and Chairman

Date: March 17, 2025

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

SIGNATURE	TITLE	DATE
/s/ Mark P. Lappe Mark P. Lappe	Chief Executive Officer and Chairman (*principal executive officer)*	March 17, 2025
/s/ Kelly D. Deck, C.P.A. Kelly D. Deck, C.P.A.	Chief Financial Officer *(principal financial officer and principal accounting officer*)	March 17, 2025
/s/ Jon Faiz Kayyem, Ph.D. Jon Faiz Kayyem, Ph.D.	Director	March 17, 2025
/s/ Douglas G. Forsyth Douglas G. Forsyth	Director	March 17, 2025
/s/ Kimberly Manhard Kimberly Manhard	Director	March 17, 2025
/s/ Kristiina Vuori, M.D., Ph.D. Kristiina Vuori, M.D., Ph.D.	Director	March 17, 2025