Annual Report | 2024

About ImmunityBio

ImmunityBio is a vertically-integrated commercial stage biotechnology company developing next-generation therapies and vaccines that bolster the natural immune system to defeat cancers and infectious diseases. The Company's range of immunotherapy platforms, alone and together, act to drive an immune response with the goal of creating durable immune memory generating safe protection against disease. We are applying our science and platforms to treating cancers, including the development of potential cancer vaccines, as well as developing immunotherapies and cell therapies that we believe sharply reduce or eliminate the need for standard high-dose chemotherapy. These platforms and their associated product candidates are designed to be more effective, accessible, and easily administered than current standards of care in oncology and infectious diseases. For more information, visit ImmunityBio.com (Founder's Vision) and connect with us on X (Twitter), Facebook, LinkedIn, and Instagram.

Our Approved Product – ANKTIVA®

The cytokine interleukin-15 (IL-15) plays a crucial role in the immune system by affecting the development, maintenance, and function of key immune cells—NK and CD8+ killer T cells—that are involved in killing cancer cells. By activating NK cells, ANKTIVA overcomes the tumor escape phase of clones resistant to T cells and restores memory T cell activity with resultant prolonged duration of complete response.

ANKTIVA is a first-in-class IL-15 receptor superagonist IgG1 fusion complex, consisting of an IL-15 mutant (IL-15N72D) fused with an IL-15Rα, which binds with high affinity to IL-15 receptors on NK, CD4+, and CD8+ T cells. This fusion complex of ANKTIVA, which confers stability and longer half-life than recombinant or native IL-15, mimics the natural biological properties of the membrane-bound IL-15Rα, delivering IL-15 by dendritic cells and drives the activation and proliferation of NK cells with the generation of memory killer T cells that have retained immune memory against these tumor clones. The proliferation of the trifecta of these immune killing cells and the activation of trained immune memory results in immunogenic cell death, inducing a state of equilibrium with durable complete responses. ANKTIVA has improved pharmacokinetic properties, longer persistence in lymphoid tissues, and enhanced anti-tumor activity compared to native, non-complexed IL-15 in-vivo.

ANKTIVA was approved by the FDA in 2024 for use in the United States with BCG for the treatment of adult patients with BCG-unresponsive non-muscle invasive bladder cancer with CIS with or without papillary tumors. For more information, visit ImmunityBio.com (Founder's Vision) and Anktiva.com.

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: 001-37507

IMMUNITYBIO, INC.

(Exact name of registrant as specified in its charter)

Delaware	**43-1979754**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
3530 John Hopkins Court San Diego, California	**92121**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (844) 696-5235

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 per share	IBRX	The Nasdaq Global Select 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 ☑

The aggregate market value of the registrant's voting and non-voting common equity held by non-affiliates, computed based on the closing price of shares of common stock on the Nasdaq Global Select Market on June 28, 2024 was approximately $980.3 million.

The number of shares of the registrant's common stock outstanding as of February 27, 2025 was 853,442,137 (excluding 163,800 shares held by a majority owned subsidiary of ours that are treated as treasury shares for accounting purposes).

DOCUMENTS INCORPORATED BY REFERENCE

As noted herein, the information called for by Part III of this Annual Report is incorporated by reference to specified portions of the registrant's definitive proxy statement to be filed in conjunction with the registrant's 2025 Annual Meeting of Stockholders, which is expected to be filed not later than 120 days after the registrant's fiscal year ended December 31, 2024.

IMMUNITYBIO, INC.

ANNUAL REPORT ON FORM 10-K
FOR THE YEAR ENDED DECEMBER 31, 2024

TABLE OF CONTENTS

Defined Terms

Unless expressly indicated or the context required otherwise, the terms "ImmunityBio," "the company," "we," "us," and "our" in this Annual Report refer to ImmunityBio, Inc., a Delaware corporation, and, where appropriate, its subsidiaries. We have also used several other terms in this Annual Report, the consolidated financial statements and accompanying notes included herein, most of which are defined below:

Term	Definition
2014 Plan	NantKwest, Inc. 2014 Equity Incentive Plan
2015 Plan	ImmunityBio, Inc. 2015 Equity Incentive Plan
2015 Share Repurchase Program	Board of Directors-approved share repurchase program
3M IPC	3M Innovative Properties Company
3PL Agent	logistics agent
401(k) Plan	401(k) retirement and savings plan
AAHI	Access to Advanced Health Institute
ACA	Affordable Care Act
ADCC	antibody-dependent cellular cytotoxicity
ALC	absolute lymphocyte count
Altor	Altor BioScience, LLC
America Invents Act	Leahy-Smith America Invents Act
Amyris	Amyris, Inc.
ANC	absolute neutrophil count
aNK	activated NK cells
ANKTIVA®	Proprietary name for N-803 (formerly ALT-803), our novel IL-15 receptor superagonist complex (nogapendekin alfa inbakicept-pmln) currently approved for use in the United States with BCG for the treatment of adult patients with BCG-unresponsive non-muscle invasive bladder cancer with carcinoma *in situ* with or without papillary tumors, and currently in clinical development for other indications.
Annual Report	Annual Report on Form 10-K for the year ended December 31, 2024
Approved product	ANKTIVA
ART	anti-retroviral therapy
ASC	Accounting Standards Codification
ASCO	American Society of Clinical Oncology
ASU	Accounting Standards Update
Athenex	Athenex, Inc.
ATM	"at-the-market" sales agreement
ATRA	American Taxpayer Relief Act of 2012
BCG	Bacillus Calmette-Guérin (TICE® BCG approved for use in the U.S.)
Beike	Shenzhen Beike Biotechnology Co. Ltd.
BLA	Biologics License Application
bNAbs	broadly-neutralizing antibodies
BPCIA	Biologics Price Competition and Innovation Act of 2009
Brink	Brink Biologics, Inc.
Cambridge	Cambridge Equities, LP
CAR	chimeric antigen receptor
CCPA	California Consumer Privacy Act of 2018
CEO	chief executive officer

Term	Definition
CFO	chief financial officer
cGMP	current Good Manufacturing Practice
China	when used in connection with the RIPA, People's Republic of China, Hong Kong and any territories controlled by the People's Republic of China
CI	confidence interval
CIO	chief information officer
CIS	carcinoma *in situ*
Clinic	Immuno-Oncology Clinic, Inc.
Closing Date	when used in connection with the RIPA, December 29, 2023
CMC	Chemistry, Manufacturing and Controls
CMO	contract manufacturing organization
CMS	Centers for Medicare & Medicaid Services
Code	Internal Revenue Code of 1986, as amended
CODM	chief operating decision maker
CPI	checkpoint inhibitor
CPRA	California Privacy Rights Act
CR	complete response
CRADA	Cooperative Research and Development Agreement
CRL	complete response letter
CRO	contract research organization
CVR	contingent value right
DAMPs	damage-associated molecular patterns
DGCL	Delaware General Corporation Law
DOD	U.S. Department of Defense
DSCSA	Drug Supply Chain Security Act
Duley Road	Duley Road, LLC
Dunkirk Facility	a leasehold interest in a cGMP ISO Class 5 pharmaceutical manufacturing space in western New York
EAP	Expanded Access Program
EEA	European Economic Area
EGFR	epidermal growth factor receptor
EMA	European Medicines Agency
ERM	Enterprise Risk Management
EU	European Union
Exchange Act	Securities Exchange Act of 1934, as amended
Exyte	Exyte U.S., Inc.
FASB	Financial Accounting Standards Board
FCA	False Claims Act
FCPA	U.S. Foreign Corrupt Practices Act
FD&C Act	Federal Food, Drug, and Cosmetic Act
FDA	U.S. Food and Drug Administration
FDASIA	Food and Drug Administration Safety and Innovation Act of 2012
FIFO	First In First Out inventory method

Term	Definition
FSMC	Fort Schuyler Management Corporation, a not-for-profit corporation affiliated with the State of New York
FTC	Federal Trade Commission
FTO	freedom-to-operate
FVO	fair value option
GBM	glioblastoma multiforme
GCP	Good Clinical Practice
GDPR	General Data Protection Regulation
GlobeImmune	GlobeImmune, Inc.
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
hAd5	human adenovirus serotype 5
haNK	high-affinity NK
Hatch-Waxman Act	Drug Price Competition and Patent Term Restoration Act of 1984
HCPCS	Healthcare Common Procedure Coding System, a set of standardized codes used in the U.S. to describe specific medical procedures, services, equipment, medications, and supplies.
HCW	HCW Biologics, Inc.
HHS	U.S. Department of Health and Human Services
HIPAA	Health Insurance Portability and Accountability Act of 1996
HITECH	Health Information Technology for Economic and Clinical Health Act
HIV	human immunodeficiency virus
IDE	Investigational Device Exemption
IgDraSol	IgDraSol, Inc., a subsidiary of the company
IL-15	novel interleukin 15
IND	investigational new drug
Infinity	Infinity SA LLC, as purchaser agent for affiliates of Oberland
iNHL	indolent non-Hodgkin lymphoma
IPR&D	In-process research and development
IRA	Inflation Reduction Act of 2022
IRB	Institutional review boards
IRS	Internal Revenue Service
J-code	a part of the HCPCS used to designate non-oral medications and other medical devices
LDMC	low-dose metronomic chemotherapy
LMIC	low- and middle-income countries
M-ceNK	memory-like cytokine-enhanced NK
MAA	Marketing Authorization Application
mAbs	monoclonal antibodies
MCC	Merkel cell carcinoma
mCRCP	metastatic castration-resistant prostate cancer
MDSC	myeloid-derived suppressor cells
MHC	major histocompatability complex
MHC-I	major histocompatability complex class I
MHC-II	major histocompatability complex class II

Term	Definition
MHRA	Medicines and Healthcare products Regulatory Agency
MTD	maximum tolerated dose
NAI	nogapendekin alfa inbakicept-pmln
NantBio	NantBio, Inc.
Nant Capital	Nant Capital, LLC
NantCell	NantCell, Inc., a subsidiary of the company
NANTibody	Immunotherapy NANTibody, LLC, a subsidiary of the company
NantKwest	NantKwest, Inc.
NantMobile	NantMobile, LLC
NantPharma	NantPharma, LLC
NantWorks	NantWorks, LLC, a related party
NC 2015 Plan	NantCell, Inc. 2015 Stock Incentive Plan
NCI	National Cancer Institute
NCV	Nant Cancer Vaccine
NEO	named executive officer
NHL	non-Hodgkin lymphoma
NIAID	National Institute of Allergy and Infectious Diseases
NIH	National Institutes of Health
NIH Guidelines	NIH Guidelines for Research Involving Recombinant DNA Molecules
NK	natural killer
NMIBC	non-muscle invasive bladder cancer
NOL	net operating loss
NSCLC	non-small cell lung cancer
OBA	NIH Office of Biotechnology Activities
Oberland	Oberland Capital Management LLC and its affiliates (including Purchasers as defined in the RIPA)
OFAC	U.S. Treasury Department's Office of Foreign Assets Control
PCAOB	Public Company Accounting Oversight Board (United States)
PD-1	programmed death receptor 1
PD-L1	programmed death receptor ligand
PDMA	U.S. Prescription Drug Marketing Act
PHI	Protected Health Information
PHSA	Public Health Service Act
PMA	premarket approval
PREA	Pediatric Research Equity Act
PRO	Patient Recorded Outcomes
Proxy Statement	Schedule 14A in connection with our 2025 Annual Meeting of Stockholders
PSA	prostate-specific antigen
QMSR	Quality Management System Regulation
QSR	Quality System Regulation
QUILT	QUantum Integrative Lifelong Trial
R&E	research and experimental expenditures
RAC	Recombinant DNA Advisory Committee

Term	Definition
rBCG	recombinant BCG
RDO	registered direct offering
RBCs	red blood cells
RECIST	response evaluation criteria in solid tumors
REMS	Risk Evaluation and Mitigation Strategy
RIPA	Revenue Interest Purchase Agreement
Riptide	Riptide Bioscience, Inc.
RMAT	regenerative medicine advanced therapy
RSU	restricted stock unit
SAFE	Simple Agreement for Future Equity
Sarbanes-Oxley	Sarbanes-Oxley Act of 2002
SARS-CoV-2	novel strain of the coronavirus (COVID-19)
sBLA	supplemental Biologics License Application
SEC	U.S. Securities and Exchange Commission
Section 404	Section 404 of the Sarbanes-Oxley Act of 2002
Securities Act	Securities Act of 1933, as amended
Serum Institute	Serum Institute of India Private Limited
Sorrento	Sorrento Therapeutics, Inc.
SPOA	Stock Purchase and Option Agreement
SQ	subcutaneous
SRLY	separate return limitation year
TAA	tumor-associated antigen
TCJA	Tax Cuts and Jobs Act of 2017
Term SOFR	Term Secured Overnight Financing Rate
Test Date	when used in connection with the RIPA, December 31, 2029
TF Platform	tissue factor-based fusion discovery platform
TGF-β	transforming growth factor beta
t-haNK	targeted high-affinity NK
TLR	toll-like receptor
TME	tumor microenvironment
TNBC	triple-negative breast cancer
T-reg	regulatory T cells
TriAd	Triple Antigen (CEA, MUC1, Brachyury)
UK	United Kingdom
UK GDPR	UK Data Protection Act of 2018
U.S. GAAP	accounting principles generally accepted in the United States of America
USPTO	U.S. Patent and Trademark Office
VA	Veterans Affairs
VBC Holdings	VBC Holdings, LLC, a subsidiary of the company
VIE	variable interest entity
VivaBioCell	VivaBioCell, S.p.A., a wholly-owned subsidiary of VBC Holdings

PART I

ITEM 1. BUSINESS.

Forward-Looking Statements

This Annual Report contains forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act that are based on our management's beliefs and assumptions and on information currently available to our management. Forward-looking statements include, but are not limited to:

- our ability to successfully commercialize ANKTIVA;
- our ability to obtain incremental approvals for ANKTIVA for new indications from the FDA or clearances or approvals from international regulatory agencies for the treatment of patients with NMIBC or other indications;
- potential future uses and applications of ANKTIVA, including as a lymphopenia rescue agent, and use in cancer vaccines and across multiple tumor types;
- our ability to develop next-generation therapies and vaccines that complement, harness, and amplify the immune system to defeat cancers and infectious diseases;
- our ability to obtain additional financing to fund our operations and complete the commercialization of our approved product and the development and commercialization of our other product candidates;
- our ability to meet our payment obligations under the RIPA and to service the interest on our related-party promissory note and repay such note, to the extent required;
- our ability to comply with the terms, conditions, covenants, restrictions, and obligations set forth in the RIPA and related transaction documents;
- our expectations regarding the potential benefits of our strategy and technology;
- our ability to forecast operating results and make period-to-period comparisons predictive of future performance due to fluctuations in warrant and derivative values;
- our expectations regarding the operation and effectiveness of our product candidates and related benefits;
- our ability to utilize multiple modes to induce cell death;
- our beliefs regarding the benefits and perceived limitations of competing approaches, and the future of competing technologies and our industry;
- details regarding our strategic vision and planned product candidate pipeline;
- our beliefs regarding the success, cost and timing of our product candidate development activities and current and future clinical trials and studies, including study design and the enrollment of patients;
- the timing of the development and commercialization of our other product candidates;
- our expectations regarding our ability to utilize the Phase 1/2 aNK and haNK® clinical trials data to support the development of our product candidates, including our taNK, t-haNK™, MSC, and M-ceNK™ product candidates;
- our expectations regarding the development, application, commercialization, marketing, prospects and use generally of our product candidates, including hAd5 constructs, and PD-L1 t-haNK and M-ceNK;
- the timing or likelihood of regulatory filings or other actions and related regulatory authority responses in the U.S. and jurisdictions outside of the U.S., including any planned IND, BLA, NDA or MAA or similar filings or pursuit of accelerated regulatory approval pathways or orphan drug status and *Breakthrough Therapy, Fast Track* or RMAT designations and any designation's eventual impact on BLA submission or approval timing and or approval probability;
- our ability to implement an integrated discovery ecosystem and the operation of that planned ecosystem, including being able to regularly add neoepitopes and subsequently formulate new product candidates;
- the ability and willingness of strategic collaborators to share our vision and effectively work with us to achieve our goals;

- the ability and willingness of various third parties to engage in research and development activities involving our product candidates, and our ability to leverage those activities;
- our ability to attract additional third-party collaborators;
- our expectations regarding the ease of administration associated with our product candidates;
- our expectations regarding patient compatibility associated with our product candidates;
- our beliefs regarding the potential markets for our product candidates and our ability to serve those markets;
- our expectations regarding the timing of enrollment and submission of our clinical trials, and protocols and timing of data read-outs related to such trials;
- our ability to produce a cytokine fusion protein, a DNA or recombinant protein vaccine, or a cell therapy;
- our beliefs regarding the potential manufacturing and distribution benefits associated with our product candidates, and our third-party CMOs' abilities to follow cGMP standards to scale up the production of our product candidates;
- our plans regarding our manufacturing facilities and our belief that our manufacturing is capable of being conducted in-house;
- our belief in the potential of our cytokine fusion proteins, DNA or recombinant protein vaccines, or cell therapies, and the fact that our business is based upon the success individually and collectively of these platforms;
- our belief regarding the magnitude or duration for additional clinical testing of our cytokine fusion proteins, DNA or recombinant protein vaccines, or cell therapies, along with other product candidate families;
- even if we successfully develop and commercialize specific product candidates, our ability to develop and commercialize our other product candidates either alone or in combination with other therapeutic agents;
- the ability to obtain and maintain regulatory approval of our approved product and to obtain and maintain regulatory approval of any of our other product candidates, and any related restrictions, limitations and/or warnings in the label of any approved product candidate;
- our ability to successfully commercialize ANKTIVA or any future approved products;
- the rate and degree of market acceptance of any approved products;
- our ability to attract and retain key personnel;
- the accuracy of our estimates regarding our future revenue, as well as our future operating expenses, capital requirements and needs for additional financing;
- our ability to obtain, maintain, protect, and enforce patent protection and other proprietary rights for our approved product and our other product candidates and technologies;
- the terms and conditions of licenses granted to us and our ability to license additional intellectual property relating to our product, product candidates and technology;
- our expectations regarding the results of market access initiatives and coverage under medical reimbursement policies;
- shelf life of ANKTIVA drug substance and drug product and availability of product supply;
- our global expansion efforts;
- any government shutdown or budget disruption, which could adversely affect the U.S. and global economies, and materially and adversely affect our business and/or our future BLA submissions;
- the impact on us, if any, if the CVRs held by former Altor stockholders become due and payable in accordance with their terms; and
- regulatory developments in the U.S. and foreign countries.

Forward-looking statements include statements that are not historical facts and can be identified by terms such as "anticipates," "believes," "continues," "goal," "could," "estimates," "scheduled," "expects," "intends," "may," "plans," "potential," "predicts," "indicate," "projects," "seeks," "should," "will," "would," "strategy," and variations of such words or similar expressions. and the negatives of those terms. In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. Statements of past performance, efforts, or results of our preclinical and clinical trials, about which inferences or assumptions may be made, can also be forward-looking statements and are not indicative of future performance or results. These statements are based upon information available to us as of the date of this Annual Report, and although 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 a thorough 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.

This Annual Report also contains estimates, projections and other information concerning our industry, our business, and the markets for certain diseases, including data regarding the estimated size of those markets, and the incidence and prevalence of certain medical conditions. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances reflected in this information. Unless otherwise expressly stated, we obtained this industry, business, market, and other data from reports, research surveys, studies, and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data, and similar sources.

Forward-looking statements involve known and unknown risks, uncertainties, and other factors that may cause our actual results, performance, or achievements to be materially different from any future results, performance, or achievements expressed or implied by the forward-looking statements. We discuss these risks in greater detail in Item 1A. "Risk Factors" of this Annual Report. Given these uncertainties, you should not place undue reliance on these forward-looking statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame. Also, forward-looking statements represent our management's beliefs and assumptions only as of the date of this Annual Report.

Except as required by law, we assume no obligation to update these forward-looking statements, or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future. You should read this Annual Report completely and with the understanding that our actual future results may be materially different from what we expect.

ImmunityBio, ImmunityBio Care, ANKTIVA, ThAnktiva, haNK, taNK, ceNK, NK-92, Nant Cancer Vaccine, NANT 001, NANT XL, NANT 001 and Design, QUILT, Outsmart Your Disease, Smart Therapies for Difficult Diseases, NantKwest, VivaBioCell, and Infacell are trademarks or registered trademarks of ImmunityBio, Inc., its subsidiaries and affiliates.

ANKTIVA has been approved by the U.S. FDA for use with BCG for the treatment of adult patients with BCG-unresponsive NMIBC with CIS with or without papillary tumors. Other than as set forth in such specific approved label, our product candidates, including N-803, are investigational agents that are restricted by federal law to investigational use only, and safety and efficacy have not been established by any agency, including the FDA.

This Annual Report contains references to our products and trademarks and products and trademarks belonging to other entities. Solely for convenience, trademarks and trade names referred to in this Annual Report, including logos, artwork, and other visual displays, may appear without the ® or ™ symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensor to these trademarks and trade names. We do not intend our use or display of other companies' products or trade names or trademarks to imply a relationship with, or endorsement or sponsorship of us, by any other companies.

Founder's Vision for Next-Generation Immunotherapy

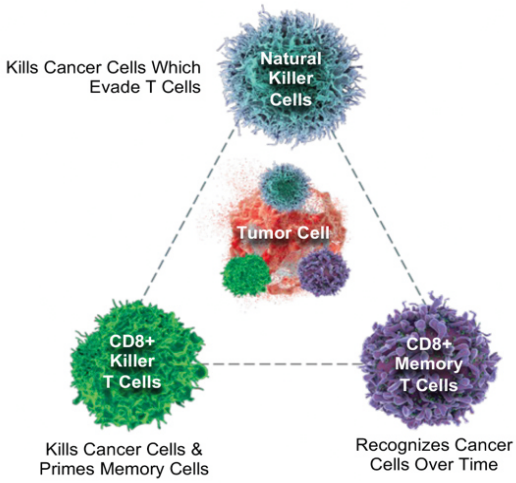
A Message from Patrick Soon-Shiong, M.D., Founder of ImmunityBio, Inc.

Founder's Vision

My 35-Year Quest to Change the Paradigm of Cancer Care by Activating the Body's Immune System and Natural Killer Cells.

Founder's Hypothesis

For the past 35 years, through my experience at UCLA treating both diabetic patients with pancreas transplants, and pancreatic cancer patients with pancreatic surgery (Whipple's), I realized that the body had opposing immune systems: on the one hand, cytotoxic systems to reject the transplanted pancreas and on the other hand immuno-evasion systems to allow pancreatic cancer to grow. By 1990, I came to realize that the common denominator was the NK cell which on the one hand interacted with killer T cells to reject a transplanted organ and on the other hand, the killer NK and T cells were blocked by the tumor, allowing the tumor cells to grow.



Activating Natural Killer, CD4+ & CD8+ T Cells

At that time, I realized that the very therapy patients were receiving (high-dose chemotherapy and radiation) aided in the destruction of the very cells patients needed to cure cancer. Of concern was the realization that the standards-of-care physicians were pursuing were based on the assumption that killing the tumor and achieving a short-term response would win the war against cancer. In fact, a short-term battle would be won by observing a response rate, but the war lost because of the destruction of important cells called lymphocytes by our chemotherapy and radiation treatment, preventing the formation of memory T cells and long-term duration of response – duration matters, T cell memory matters. Thus began the hypothesis that if we could harness the activity of lymphocytes – specifically NK and killer T cells, the potential existed to outsmart the immuno-evasion of cancer and unleash the body's immune system to treat cancer with immunotherapy for long-term overall survival and indeed even prevent cancer in patients with high risk.

However, I faced the challenge of 50 years of standards of care which relied on high-dose chemotherapy and radiotherapy. The notion that the standard-of-care would rapidly destroy these lymphocytes, the very cells needed to kill the tumor and establish T and NK cell memory, was difficult to convince the medical establishment and regulatory authorities. The possibility that our standard-of-care was indeed responsible for preventing long-term complete remissions by the inadvertent process of destroying the very system engineered in our bodies to protect against cancer and infectious disease, was the quest that required challenging. That is the mission of ImmunityBio and the recent recognition in 2025 by the FDA that ANKTIVA and PD-L1 t-haNK was granted a Regenerative Medicine Advanced Therapy (RMAT) designation for the reversal of lymphopenia in patients receiving chemotherapy and radiation therapy is a turning point for this paradigm change in cancer care.

The destruction of the NK and T cells resulting in lymphopenia (low levels of lymphocytes) correlated with poor prognosis of overall survival across multiple tumor types. With our increasing knowledge of the immune system, including the discovery of T cells, NK cells and dendritic cells, and their role in cancer suppression (immuno-surveillance) and cancer growth when the tumor develops mechanisms to hide from the cytotoxic effects of NK and T cells (immune evasion), it became time to re-visit immunotherapy. Most are familiar with the breakthrough of CPI therapy, represented by antibodies that target either PD-1, PD-L1, or other molecules that act to inhibit immune cell (specifically T cell) responses to cancer. But even the efficacy of CPI therapies can be undermined by lymphopenia (lack of T cells), making the rescue of lymphopenia an overarching goal of my approach to cancer therapy.

This vision, which I have pursued for decades, is the transformation in the paradigm for cancer care by treating the host and activating the immune system (NK cell and killer T cell) resulting in immunogenic cell death and inducing long-term duration of response with the generation of memory T cells and memory NK cells. On the other hand, standards of care have been addressing the tumor itself (rather than the host immune system) with high-dose chemotherapy for short-term response gains. A paradigm change would be to address the host's immune system by activating the host immune system by utilizing the tumor in the body as an antigenic source to generate a long-term durable response to the activated NK cell, T cell and memory T cell. In this way, a therapeutic cancer vaccine could be developed. Along this journey, it has been difficult to convince academia, medical cancer centers, the FDA and even the pharmaceutical industry that existing treatment paradigms for cancer are based on misplaced assumptions utilizing high-dose chemotherapy and radiotherapy by "winning the battle but losing the war."

In 2017, I proposed a General Investigational Plan to study a potential therapeutic cancer vaccine applicable to all tumor types to the FDA and was given an audience with the Oncology Centers of Excellence by the FDA leadership. The hypothesis, including the request for RMAT designation presented in the plan was as follows:

> *"A paradigm change in cancer care is required in which a modernized treatment is based on the biology of the tumor independent of anatomy, utilizing molecular and immunological insights as to the dynamic state of the cancer in its evolution (elimination, equilibrium, and escape) and specifically tailored to the patient's cancer altered genome, to reinstate the patient into equilibrium.*
>
> *The notion that the tumor tissue itself could act as a source of both antigenicity and adjuvanticity is exploited by the NANT Cancer Vaccine – a universal therapeutic cancer vaccine that acts through the orchestration of the innate and adaptive immune system across all tumor types.*
>
> *We hypothesize that the normal physiological protective immune system of Elimination can be reinstated by the NANT Cancer Vaccine, first by overcoming the immunosuppressed Escape state, followed by induction of immunogenic cell death and activation of effector immune cells, with restoration of the patient to a state of Equilibrium, a paradigm change in cancer care."*

The leadership at the FDA listened to this presentation and subsequently while denying RMAT designation, authorized my request to pursue this hypothesis by performing Phase 1 and Phase 2 clinical trials I termed "QUILT" **QU**antum **I**ntegrative **L**ifelong **T**rial across certain indications including first-line and second-line NMIBC, second-line and third-line MCC, second-line and third-line metastatic pancreatic cancer, second-line or greater GBM, third-line metastatic TNBC and third-line metastatic head & neck cancer. I also coined the term "Quantum Oncotherapeutics" to highlight the concept that the TME is dynamic and very rapid changes occur based on the therapy we administer.

This authorization was seminal in my journey to prove the importance of NK and T cells and the need to orchestrate molecules which would induce the innate and adaptive immune system to result in durable overall survival and complete remissions. Over the course of the past 8 years, the findings I describe below provide support that my hypothesis was correct and a universal therapeutic cancer vaccine may be possible.

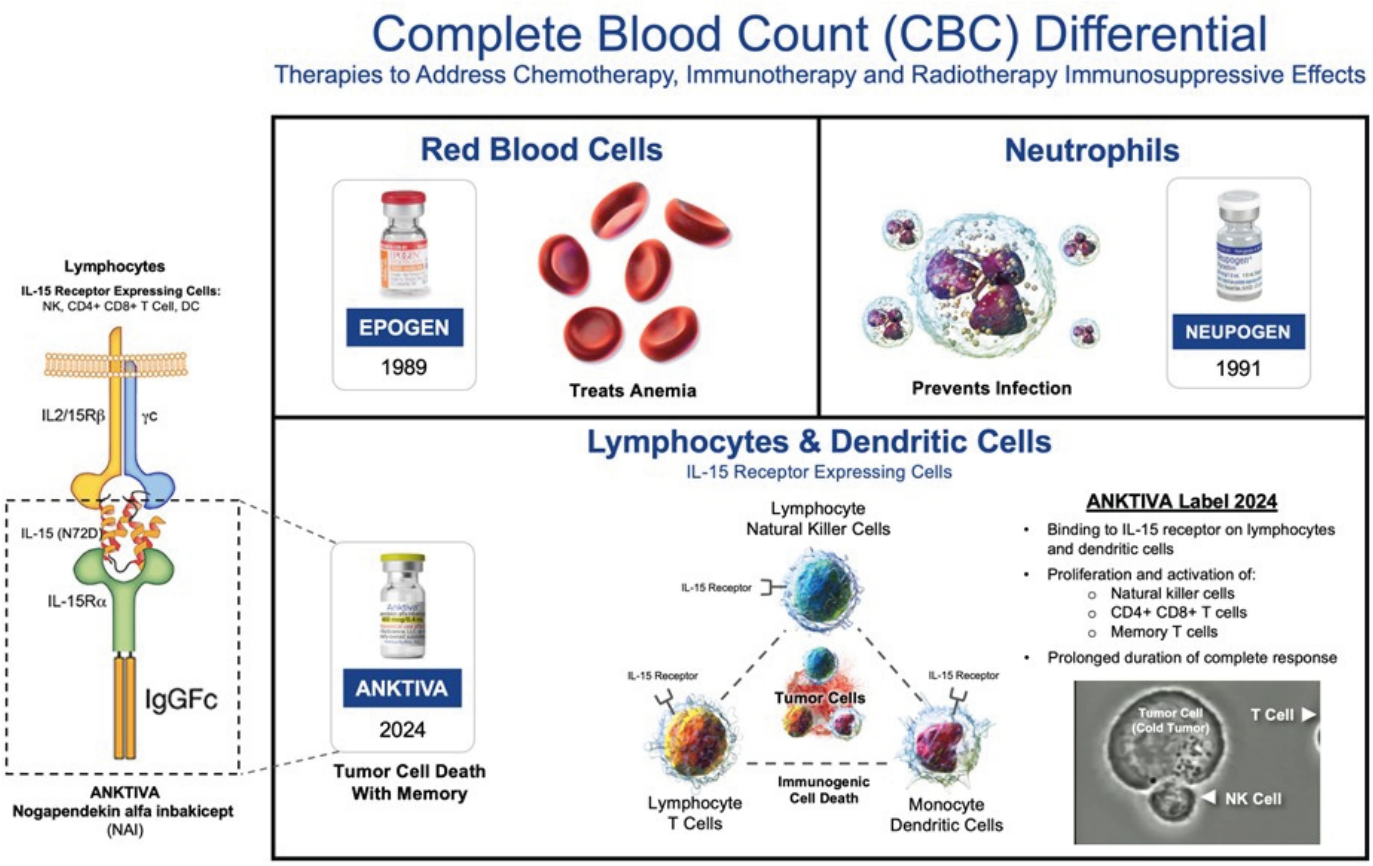
For the first time in 50 years, oncologists may now have a reason to pay more attention to a complete blood count analysis of lymphocytes (NK & T cells) as the RMAT designation – granted on February 27, 2025 for ANKTIVA and PD-L1 t-haNK in combination with standard-of-care chemotherapy/radiotherapy indicated for the reversal of lymphopenia and treatment of multiply relapsed locally advanced or metastatic pancreatic cancer – is developed. Below is a summary of this journey. It is my hope that the concept of ALC will begin to be recognized by oncologists and the ratio of ANC to ALC will become a key biomarker of the current status of a patient with cancer and a predictor of outcome.

The Breakthrough of NK and T Cell Rescue by IL-15 Receptor Superagonist – Overcoming Lymphopenia

The standard analysis performed by oncologists following chemotherapy is the evaluation of the CBC with the differential subset of cells that make up the circulating blood levels. The focus of oncologists today in the review of the differential are red blood cells, platelet count and neutrophils. Remarkably, very little to no attention is given to lymphocyte count – the very cells (killer T cells and NK cells) that are critical for killing the tumor. Instead, in addition to platelet counts, oncologists today focus on the following subset of cells in the CBC:

- Red Blood Cells (RBCs) – to determine anemia as a consequence of the chemotherapy
- Neutrophils (ANC) – to determine the neutrophil level to avoid infection as a consequence of the chemotherapy

Oncologists are familiar with monitoring RBCs and neutrophils since therapies are available to mitigate the consequences of anemia and neutropenia by administration of, for example, EPOGEN to manage anemia and NEUPOGEN to manage neutropenia. Yet there is little focus on the cells of importance in the blood system that are directly involved in the killing of the tumor, **lymphocytes (NK and T cells)**, as reflected by the lymphocyte count and percentage of lymphocytes relative to the neutrophils. It is likely that attention was rarely given to the **lymphocyte count** and the neutrophil to lymphocyte ratio (NLR) by caregivers managing cancer patients because no therapy existed to mitigate lymphopenia. Now, we believe our IL-15 receptor superagonist ANKTIVA (also known as N-803; molecular name nogapendekin alfa inbakicept-pmln, which has been approved for the treatment of adult patients with BCG-unresponsive NMIBC with CIS with or without papillary tumors), provides a potential treatment for lymphopenia.



We believe that NAI may be the answer to the challenge oncologists have faced for the last 50 years, that is, how to address lymphopenia. The efficacy of immune CPIs, while a major step forward in cancer care, depends on the presence of T cells as well as the presence of the receptor to T cells on tumors (MHC-I and MHC-II). It stands to reason that with lymphopenia (low T cells) or MHC-I loss, T cell activity would be inhibited, and CPI therapy would fail. However reversing lymphopenia and overcoming low NK and T cell activity could result in the rescue of T cells and CPI failures. Just as **EPOGEN** and **NEUOPOGEN** are used across all tumor types regardless of the anatomy, we believe that NAI (proposed as ANKTIVOGEN in this potential indication), due to its ability to rescue lymphopenia by proliferation and activation of NK and T cells, has the potential to, if approved, overcome lymphopenia across all tumor types.

We believe the FDA authorization of RMAT designation for NAI and PD-L1 t-haNK in combination with standard-of-care chemotherapy/radiotherapy indicated for the reversal of lymphopenia and treatment of multiply relapsed locally advanced or metastatic pancreatic cancer places ImmunityBio on the path to a potential paradigm change in cancer care.

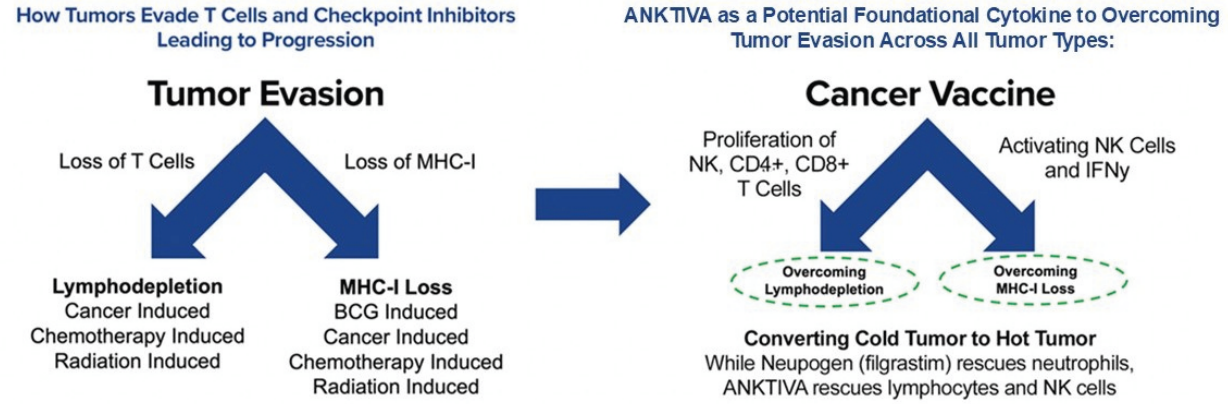
Lymphopenia in cancer and its effects on response rates to chemo and immunotherapy have been studied in detail. Studies performed in large patient populations with advanced cancers confirm that regardless of histological subtype and treatment, global and CD4+ lymphopenia are powerful independent predictors of risk of high-grade toxicity to chemotherapy. In addition, peripheral lymphopenia, pre-existing or induced by therapies in patients with metastatic solid tumors, strongly impacts their survival and CD4+ lymphopenia is a powerful marker of reduced survival. Different published studies exploring the impact of global lymphopenia or NK and T cell subsets on relapse-free survival and overall survival in patients with solid tumors show lymphocyte thresholds (% lymphopenia) generally <1,000 per microliter of blood leading to elevated relative risk scores for both relapse-free survival (1.35-3.81) and overall survival (1.25-7.70).

Tumor Type	N	Type of lymphopenia evlauated	Lymphocyte Threshold (% lymphopenia)	RFS (Cox Analysis)			OS (Cox Analysis)		
				RR	IC 95%	P value	RR	IC 95%	P value
Sarcoma	193	Overall Lymphopenia	<1000 (24%)	Not evaluated			1.46	1.0-2.1	0.05
Ewing Sarcoma	24	Overall Lymphopenia	<500 (33%)	Not evaluated			4.34	1.35-14.28	0.007
Renal Cell Carcinoma	424	Overall Lymphopenia	≤1300 (28.06%)	Not evaluated			1.75	1.14-2.67	0.0102
Colon Carcinoma	260	Overall Lymphopenia	<1000 (19%)	1.56	1.0-2.43	0.048	2.35	2.34-4.14	0.003
Breast Carcinoma	195	Overall Lymphopenia	<1000 (28.7%)	1.82	1.27-2.59	0.001	2.23	1.36-3.65	0.001
Non Hodgkin Lymphoma	322	Overall Lymphopenia	<1000 (25%)	1.71	1.2-2.4	0.002	1.48	1.03-2.21	0.04
Diffuse large B cell lymphoma (DLBCL)	151	Overall Lymphopenia	≤1000 (35.8%)	Not evaluated			2.38	1.29-4.34	0.005
DLBCL	221	Overall Lymphopenia	<1000 (38.9%)	2.72	1.61-4.60	<0.001	2.51	1.38-4.58	0.003
DLBCL	89	Overall Lymphopenia	<840 (23%)	3.81	1.72-8.42	0.0009	4.38	1.88-13.28	0.0012
Follicular Lymphoma	228	Overall Lymphopenia	≤1000 (28%)	Not evaluated			1.72	1.33-2.24	$<10^{-4}$
Hodgkin Lymphoma	476	Overall Lymphopenia	<600 (18.06%)	1.59	0.96-2.58	0.06	1.25	0.74-2.15	0.4
Hodgkin Lymphoma	2497	Overall Lymphopenia	<600 (11%)	1.38		0.002	Not evaluated		
Multiple Myeloma	537	Overall Lymphopenia	<1400 (62%)	Not evaluated			1.71	1.53-2.35	$<10^{-4}$
ATLL	60	Overall Lymphopenia	<1000 (35.6%)	1.93		0.004	2.37		0.0003
PTCLU	69	Overall Lymphopenia	<1000 (38%)	Not evaluated			4.0	1.9-8.3	$<10^{-4}$
PTCL-NOS	118	Overall Lymphopenia	1000 (30.5%)	1.94	1.19-3.18	0.008	2.24	1.33-3.78	0.002
Breast Carcinoma	287	Overall Lymphopenia	<1000 (27%)	1.48	1.1-2.0	0.01	1.8	1.3-2.4	0.0002
Breast Carcinoma	195	Overall Lymphopenia	<1000 (28.7%)	1.82	1.27-2.59	0.001	2.23	1.36-3.65	0.001
Breast Carcinoma 1st relapse	128	Overall Lymphopenia	<1000 (44.27%)	Not evaluated			1.8	1.15-2.82	0.01
Breast Carcinoma 1st relapse 1^{st} relapse	103	Overall Lymphopenia	<700 (22.3%)	Not evaluated			2.03	1.17-3.50	0.016
Breast Carcinoma 1st relapse 1^{st} relapse	103	$CD4^+$ Lymphopenia	≤450 (53.4%)	Not evaluated			2.50	1.57-3.98	$<10^{-4}$
Breast Carcinoma >2^{nd} relapse	101	$CD4^+$ Lymphopenia	≤450 (70.3%)	1.35	0.87-1.1	0.183	1.69	1.04-2.78	0.036
Metastatic Solid Tumors	219	$CD4^+$ Lymphopenia	≤450 (47.9%)	Not evaluated			1.5	1.1-2.1	0.017
Metastatic Solid Tumors	213	$CD4^+$ Lymphopenia	<450 (49.7%)	Not evaluated			7.7[a]	1.6-35[a]	0.007[a]
Non Hodgkin Lymphoma	88	$CD8^+$ Lymphopenia	<200	Not evaluated			3.30	1.21-9.0	0.01
Follicular Lymphoma	75	NK cells Lymphopenia	<150 (44%)	Not evaluated			6.73	0.76-59	0.08
DLBCL	136	NK cells Lymphopenia	≤80 (37.5%)	1.81	1.27-2.57	0.001	Not evaluated		

[a] Analysis of the risk of early death;

We believe the FDA approval of ANKTIVA with BCG for treatment of adult patients with BCG-unresponsive NMIBC with CIS with or without papillary tumors in 2024 and the recent RMAT designation with ANKTIVA and PD-L1 t-haNK provides the opportunity for the first FDA-approved cancer therapy (ANKTIVA in BCG Unresponsive NMIBC CIS) to be extended in patients receiving standard-of-care chemotherapy and radiotherapy, that has the potential to reverse lymphopenia – meaning the ability to resuscitate and rescue NK and T cells – the very cells of critical importance for immunogenic cell death and long-term memory against the tumor. Through its mechanisms of action to proliferate NK and T cells (as described on its label) and therefore rescue lymphopenia, I believe ANKTIVA has the potential to be the backbone of my vision for 'Immunotherapy 2.0' that could launch a new era and paradigm change in the treatment of cancer across all tumor types by driving memory T and NK cells with durable remission of the disease.

ANKTIVA overcomes tumor evasion by mitigating both the loss of T cells (lymphopenia) and the loss of the ligand to T cells on the tumor (MHC-I loss). The mechanism of potentially overcoming cold tumors will be discussed in detail further below.

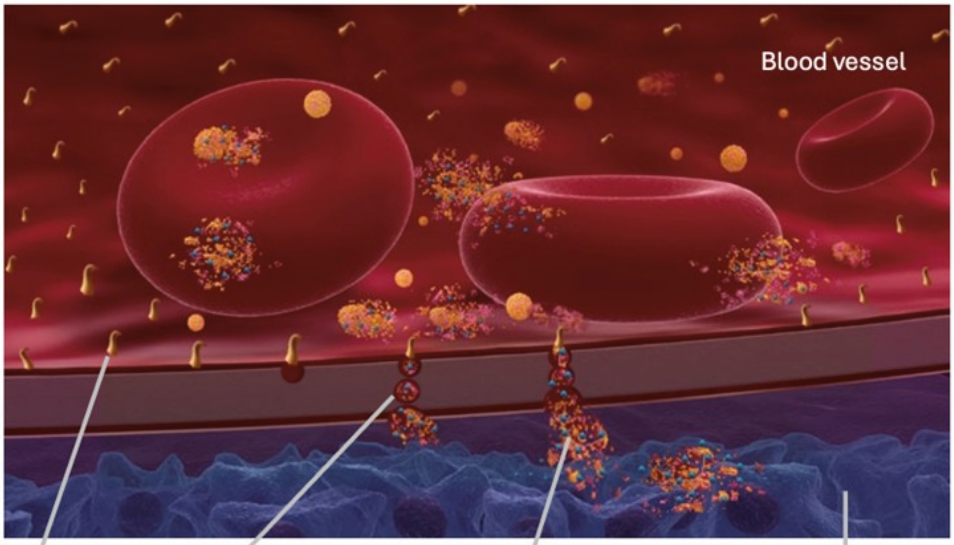


ABRAXANE – Immunogenic Cell Death in the Tumor Microenvironment (2005: FDA Approval)

As the first step in my quest to change the paradigm of cancer care previously based on toxic high-dose chemotherapy and/or radiation, I left academia (UCLA) to develop the nation's first albumin-bound nanoparticle of paclitaxel (nab-paclitaxel), ABRAXANE, and to institute the concept of LDMC to elicit a vaccine-like effect. LDMC is chemotherapy not used at the MTD to kill the tumor, but rather to stress the tumor and elicit release of antigens to allow the killer cells surrounding the tumor (macrophages, T cells and NK cells), to induce immunogenic cell death.

Even today, the concept of albumin-bound therapy to concentrate drug at the tumor site is not always fully appreciated by the oncology community. ABRAXANE was developed to exploit the biology of the concept of **transcytosis** whereby the transport of albumin-bound paclitaxel across the endothelial blood vessel layer to the TME is accomplished through the gp60 receptor and the Caveolin pathway leading to entry of paclitaxel in the TME and the production of stress molecules in the tumor (DAMPs), while at the same time activating the killer macrophages (M2 suppressive macrophages to M1 killer macrophages). ABRAXANE was approved by the FDA in 2005 for the treatment of breast cancer after failure of combination chemotherapy for metastatic diseases or relapse within six months of adjuvant chemotherapy and now also has FDA approval for patients with lung and pancreatic cancer in certain indications.

Abraxane Approved in 2005



ANKTIVA – IL-15 Receptor Superagonist Rescuing Lymphocytes and Overcoming MHC-I Loss (2024: FDA Approval)

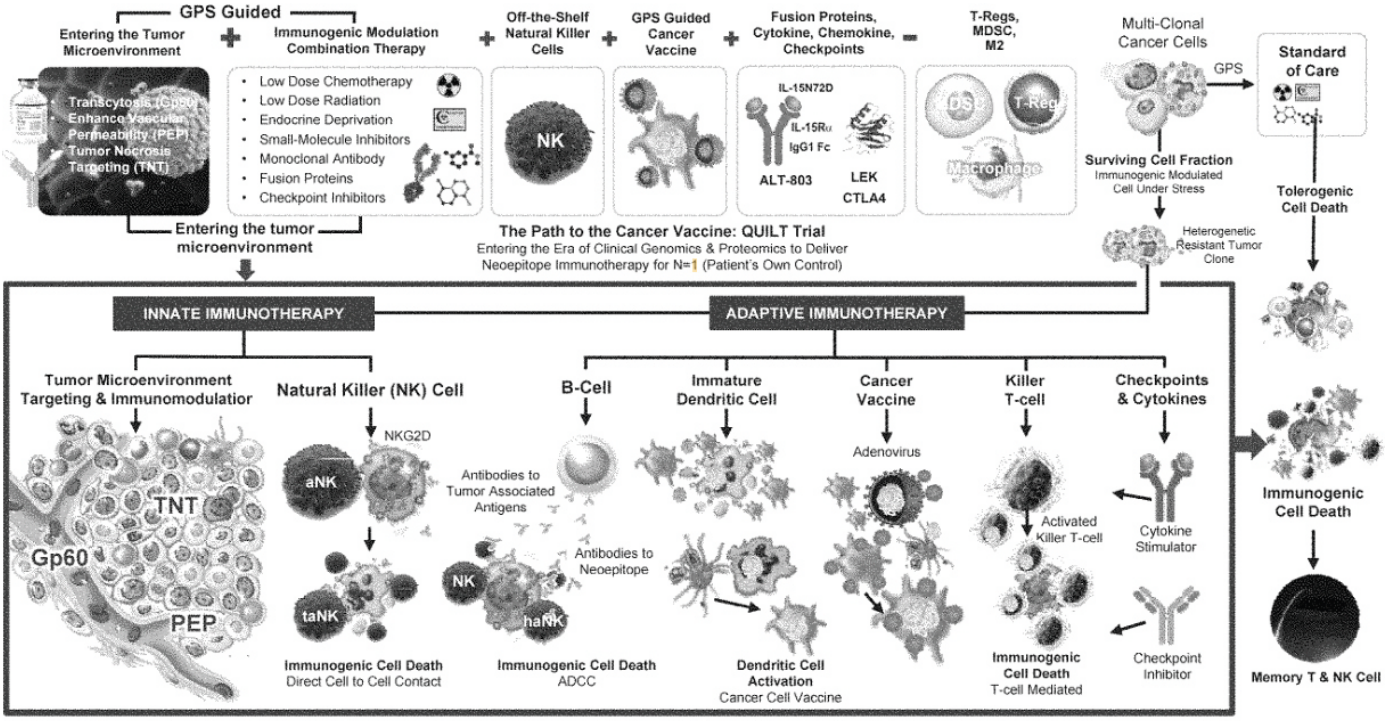
With ABRAXANE as the first pillar in this quest to change the paradigm of care, I then turned my attention to addressing lymphopenia and unleashing the "triangle offense" via the IL-15 receptor superagonist ANKTIVA.

In 2024, ANKTIVA with BCG for the treatment of adult patients with BCG-unresponsive NMIBC with CIS with or without papillary tumors was approved by the FDA, who authorized the description of the mechanism of action in the label as:

Anktiva
Nogapendekin alfa inbakicept-pmln

Nogapendekin alfa inbakicept-pmln is an IL-15 receptor agonist. IL-15 signals through a heterotrimeric receptor that is composed of the common gamma chain (γc) subunit, the beta chain (βc) subunit, and the IL-15-specific alpha subunit, IL-15Rα. IL-15 is trans-presented by the IL-15 receptor α to the shared IL-2/IL-15 receptor (βc and γc) on the surface of CD4+ and CD8+ T cells and NK cells. Binding of nogapendekin alfa inbakicept-pmln to its receptor ***results in proliferation and activation of NK, CD8+, and memory T cells without proliferation of immuno-suppressive T-reg cells.*** *In vivo, intravesicular nogapendekin alfa inbakicept-pmln alone or in combination with BCG showed anti-tumor activity when compared to BCG alone, in a carcinogen-induced model of bladder cancer in immunocompetent rats.*

I believe this potentially universal therapeutic vaccine, sometimes referred to as NCV (U.S. Patent #US11071774-B2), could be able to coordinate the release of antigens from tumor cells (DAMPs/neoantigens and/or shared tumor-associated antigens, TAAs) or provision of vaccine antigens with support for immune-cell activity, including cells of both the innate and adaptive immune systems, to achieve a vaccine-like effect. ANKTIVA, due to its mechanism of proliferating and activating innate (macrophages, NK cells, dendritic cells) and adaptative (T cells, iNKT cells, and memory T cells) immune cells provides the vital stimulus needed to establish immune memory.



Thus, I believe ANKTIVA has the potential to become the backbone for a cancer vaccine not only to potentially cure cancer (long-term duration free of disease) but also to prevent cancer. An example of the possibility of prevention is in subjects with Lynch Syndrome, a genetic condition that puts them at significantly higher risk for cancer, and with an earlier age of onset. Currently, ANKTIVA plus vaccines that deliver tumor associated antigens via adenovirus, relevant to Lynch Syndrome are being tested in clinical trials with subjects with Lynch Syndrome for their ability to prevent cancer onset. If efficacious, this novel treatment could help support that a universal cancer vaccine is indeed possible.

Quantum Oncotherapeutics – A Potential Universal Therapeutic Cancer Vaccine

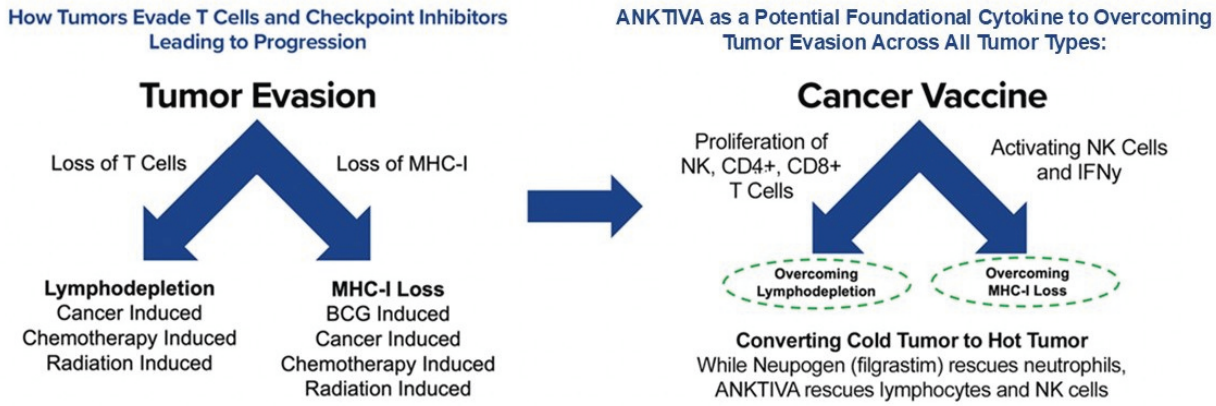
Changing the paradigm and convincing oncologists of the need to avoid high-dose chemotherapy and implement a treatment protocol that activates the patient's immune system rather than destroying the NK cells and T cells remains a difficult task even today.

In 2017, the FDA allowed ImmunityBio (formerly NantKwest and NantCell) to initiate a series of transformative clinical trials in which the concept of inducing immunogenic cell death (ICD) was pursued. These trials entitled "QUILT" QUantum Integrative Lifelong Trials were seminal in the pursuit of a universal cancer vaccine. The clinical protocols shared an approach that followed my vision of inducing DAMPs, avoiding high-dose chemotherapy, educating T cell via dendritic cell activation and inducing NK, CD4+ and CD8+ T cell proliferation in combination with off-the-shelf CAR-NK cell therapy to overcome immunosuppressive T-reg cells and myeloid-derived suppressive cells (MDSCs). The findings from the QUILT trials have confirmed the validity of the NCV approach.

In 2022, I was honored to present the concept of "Quantum Oncotherapeutics" providing updates and receiving authorization to proceed with the QUILT trials and by 2025 met with the FDA to present the update of these trials.

The Challenges of Checkpoint Failure Facing Oncologists: Immunotherapy 2.0 Beyond Checkpoints

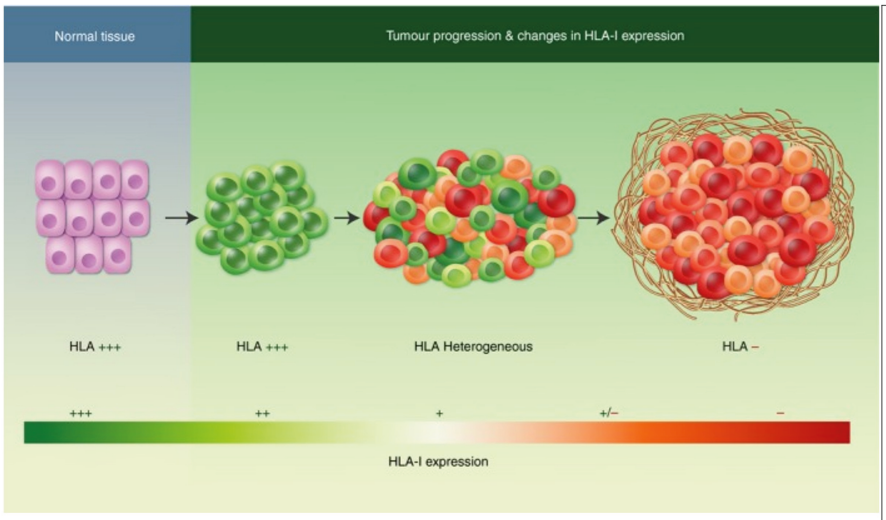
By 2024, the FDA had approved the use of CPIs (pembrolizumab, nivolumab, etc.) across 17 different tumor types. However, at the 2024 ASCO Annual Meeting I believe it became apparent that responses to CPIs were frequently fleeting and that CPIs were not effective in so-called "cold tumors." The cold tumor is defined as lacking sufficient T-cell infiltration or activity of the T cells, even with use of a CPI, in the TME, and the loss of MHC-I, the binding site on the tumor for the T-cell receptor. Thus, the lack of effect in cold tumors is driven by fewer T cells (lymphopenia) and selection of cancer cell clones without the receptor for T cells to bind to MHC-I (MHC-I loss). Given these dynamics, it is not surprising that CPIs alone often fail or elicit only transient responses.



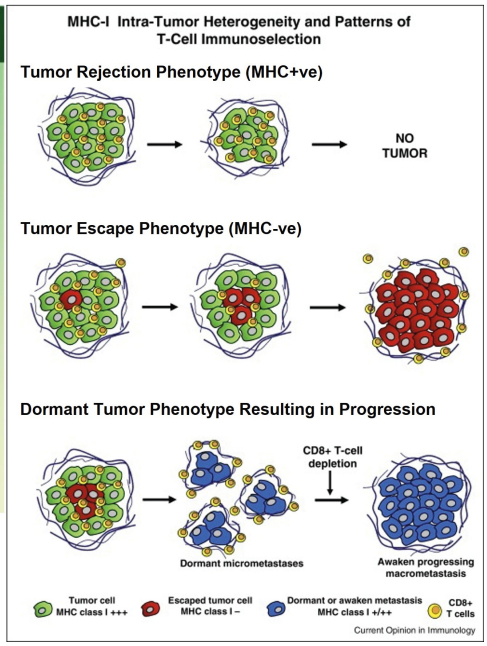
Overcoming Tumor Evasion and Converting a Cold Tumor to a Hot Tumor

The addition of ANKTIVA not only rescues T cells, but also activates NK cells that have the ability to recognize tumor cells without MHC-I expression and, as a result of increased interferon-γ (IFN-γ) secretion by the activated NK cells, also has the potential to restore MHC-I expression. All of these activities act to rescue CPIs. Thus, the combination of ANKTIVA plus a CPI represents Immunotherapy 2.0. A depiction of how ANKTIVA has the potential to convert a cold tumor to a hot tumor and rescues CPIs is provided below.

Darwinian Selection of Resistant Tumor Cells by MHC Loss: Targets for Natural Killer Cells

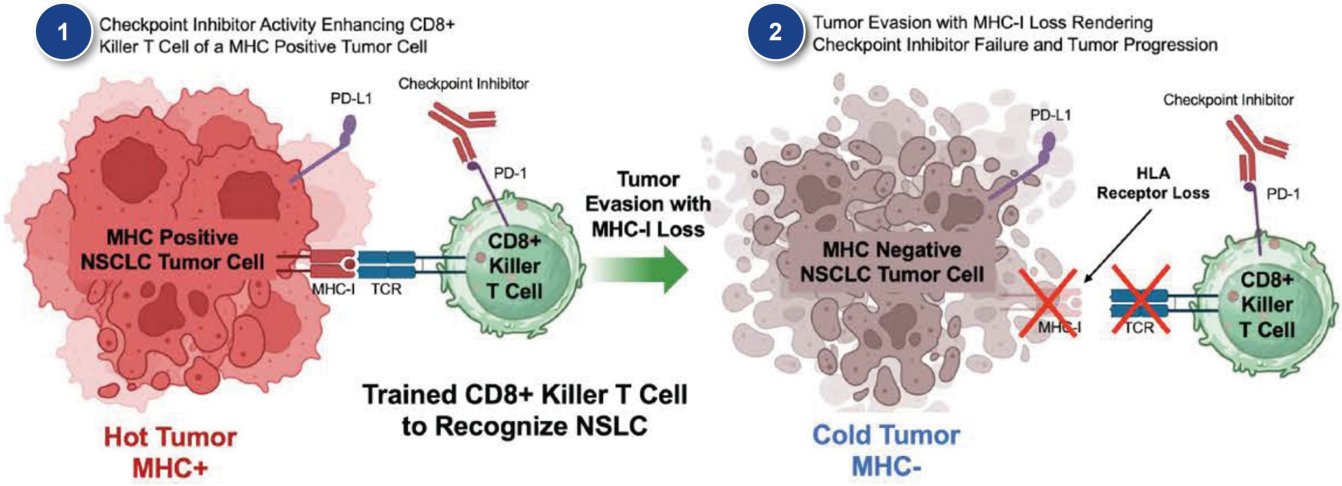


MHC Loss as the mechanism of tumor evasion and progression while on checkpoint inhibitor therapy



The loss of MHC-I molecules serves as a mechanism for tumor evasion and progression during CPI therapy. This phenomenon can be understood through the lens of Darwinian selection, where tumors that are resistant to either chemotherapy or chemo-immunotherapy emerge due to the loss of MHC-I receptors on tumor cells, which are essential for T cell recognition. These highly selected resistant cells, characterized by MHC-I loss, subsequently become targets for NK cells. NK cells are specifically designed to identify and eliminate cells that lack MHC-I expression, a process known as “missing-self” recognition.

Tumor Evasion to CD8+ Killer T Cells by MHC-I Loss and Checkpoint Inhibitor Failure with Progression



Tumor evasion to CD8+ Killer T-Cells by MHC-I Loss

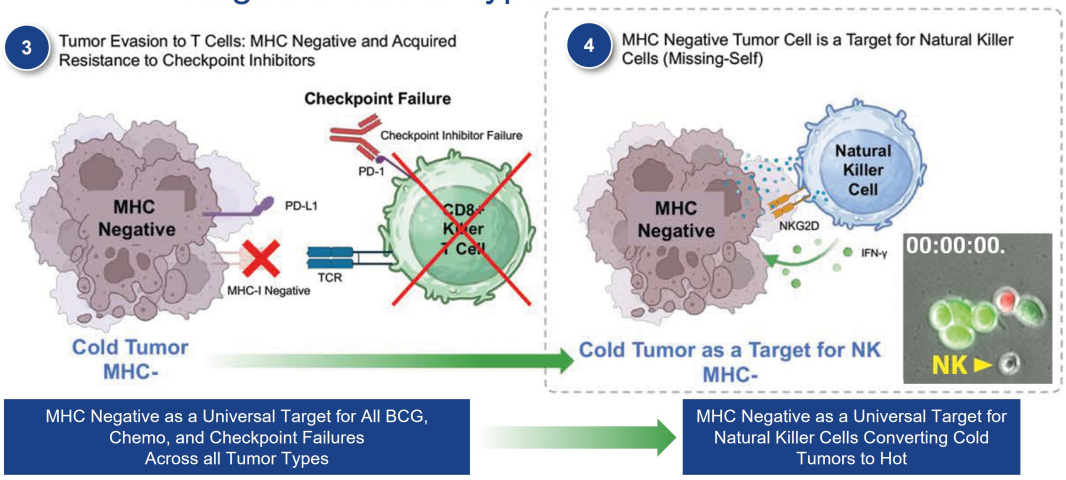
Tumor Evasion to Checkpoint Therapy with MHC Loss and Generation of a MHC-ve Cold Tumor

The evasion of tumors from checkpoint therapy through the loss of MHC-I molecules leads to the generation of MHC-I negative, or "cold" tumors. Initially, the tumor cells are "hot" and recognized by T cells activated by CPIs. However, with the loss of MHC-I, these tumor cells evade T cell detection, becoming "cold" and resulting in checkpoint therapy failure and subsequent tumor progression.

MHC Negative Tumor Cells Are a Target for Natural Killer Cells Across All MHC Negative Tumor Types

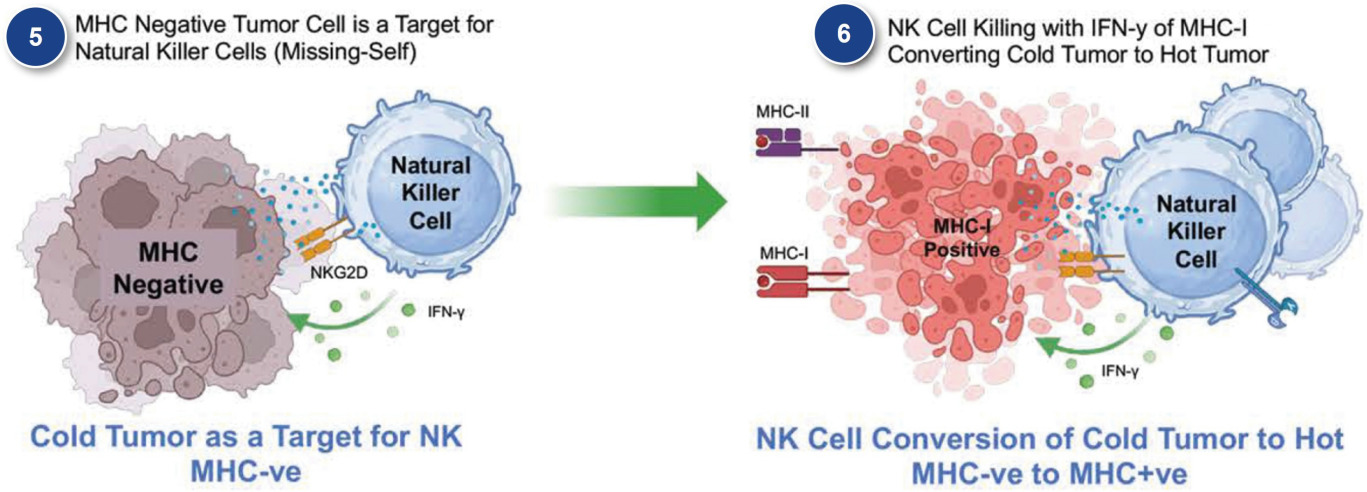
MHC-ve Tumor Cells Are a Target for Natural Killer Cells Across All MHC-ve Negative Tumor Types

MHC-ve Tumors, a Universal Target for ANKTIVA, an IL-15 Superagonist that Proliferates NK Cells



An MHC negative cold tumor cell which has evaded T cell detection and hence led to progression despite treatment with CPIs is now the target of NK cells. NK cells cytotoxicity is independent of MHC-I status and independent of PD-L1 status on the tumor cell. Thus, if NK cells could be activated and proliferated, NK cells could kill these Darwinian-selected resistant cancer cells and rescue CPIs.

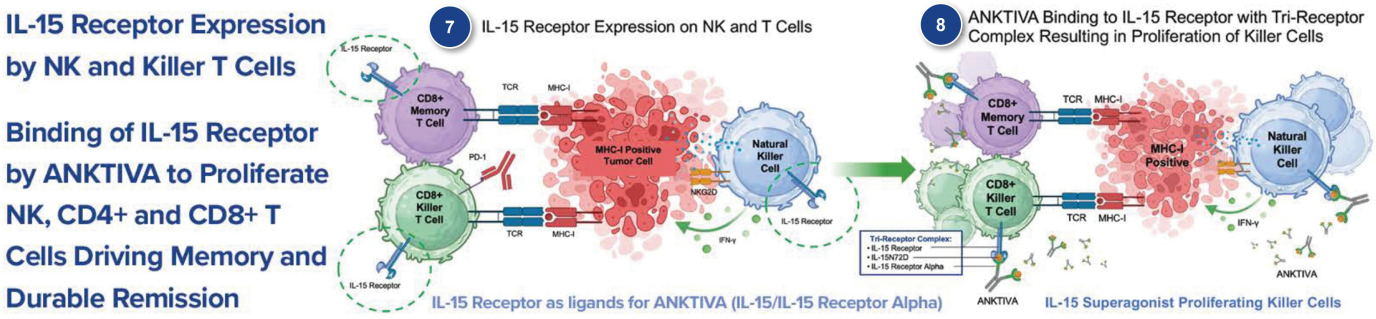
Upregulation of MHC-I and Reversal of Tumor Evasion with the Generation of IFN-γ From Activated NK Cells



Converting Cold Tumor to Hot Tumor by Natural Killer Cell Targeting MHC-ve Cold Tumor Cell with Stimulation of IFN-γ

The NK cell recognizes the MHC negative cold tumor and converts the tumor from hot to cold through IFN-γ stimulation. As a consequence, MHC-I and MHC-II are re-expressed on the tumor cell, making the cell recognizable by T cells. This dynamic activity can be enhanced by proliferation of NK, CD4+ and CD8+ T cells through IL-15 stimulation of the IL-15 receptor on NK, CD4+ and CD8+ T cells.

Anktiva Mechanism of Action: IL-15 Superagonist Proliferating NK Cells, CD8+ T Cells with Memory T Cell Inducing Durable Response with Rescuing CPIs

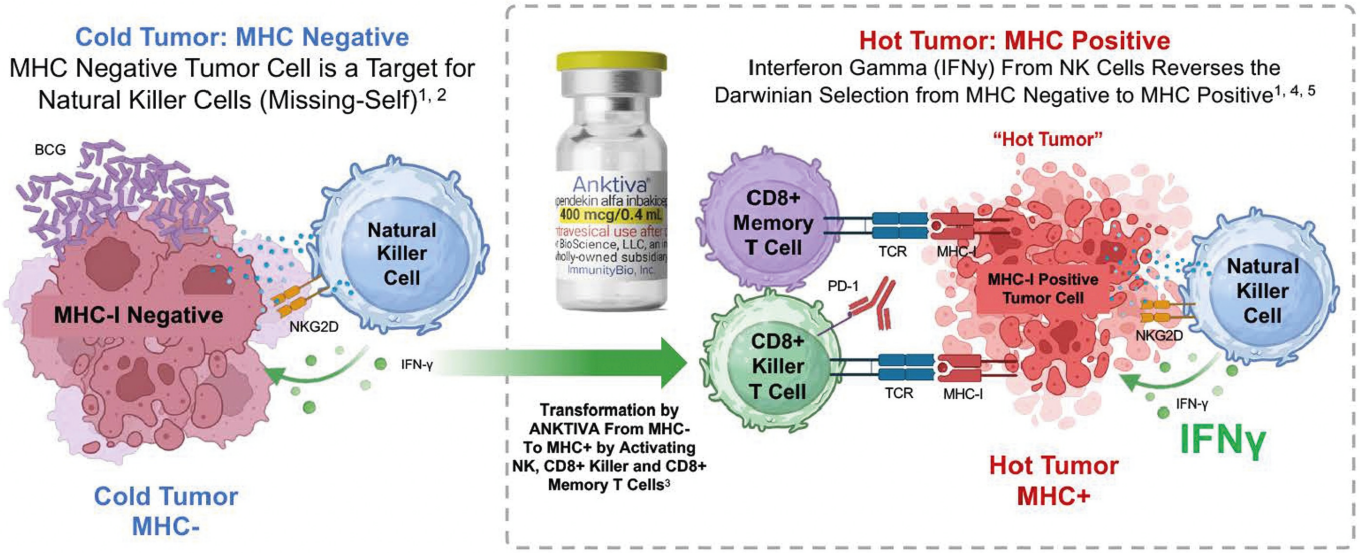


Potential for ANKTIVA to Serve as a Foundational Cytokine for a Universal Cancer Immunotherapy

ANKTIVA, an IL-15 receptor superagonist, stimulates the IL-15 receptor on natural killer cells resulting in proliferation of the NK cell and conversion of the cold tumor to hot by the NK cell recognizing the MHC negative tumor and converting the cold tumor to hot. This activity of reactivating T cells allows the rescue of CPIs against PD-1.

ANKTIVA as a Potential Backbone Across Multiple Tumor Types:

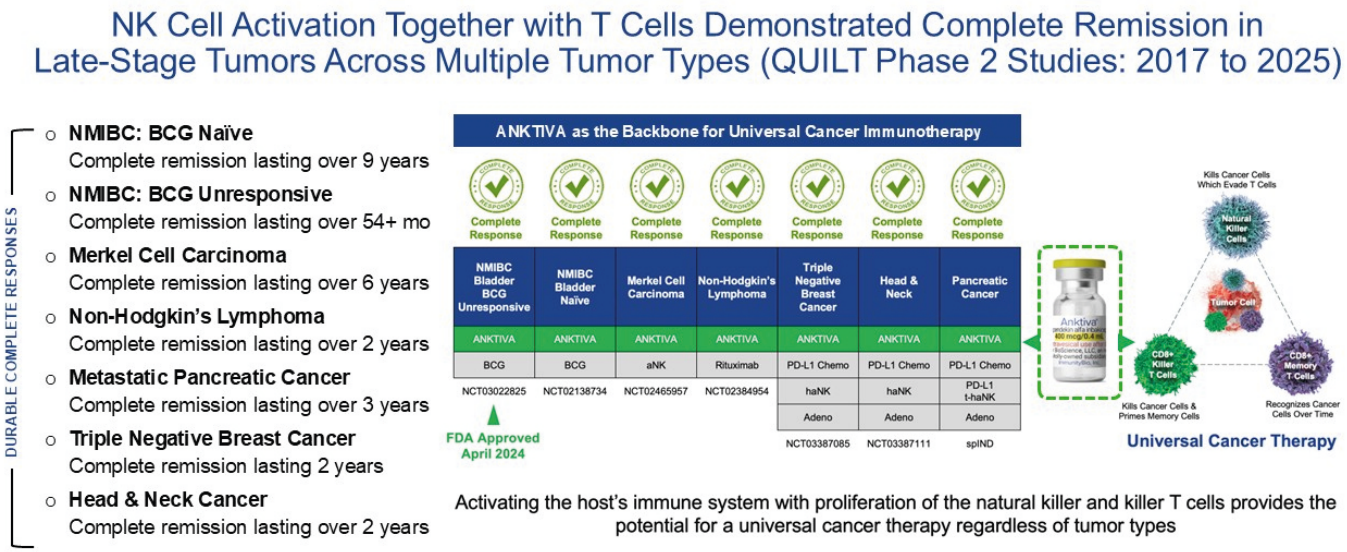
Universal Capability of Converting a Cold Tumor to a Hot Tumor Via IFN-γ Stimulation and NK Cell Activation



SUMMARY: ANKTIVA rescues and restores CD8+ killer T cells and memory T cells by converting MHC negative (cold) to MHC positive (hot) tumors through IL-15 stimulated NK cell activation and IFN-γ secretion with durable response and prolonged overall survival.

QUILT Studies Validate NCV with ANKTIVA as the Backbone

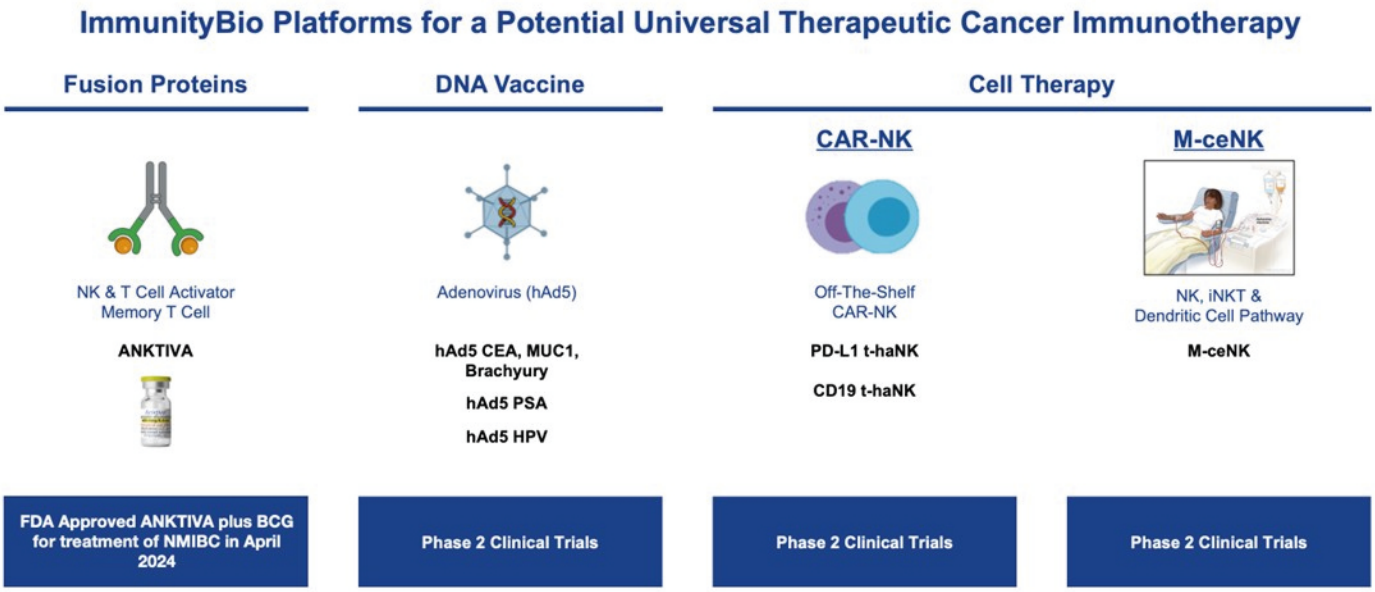
I presented findings from completed QUILT studies during a 2025 program review meeting with the FDA, including the achievement of complete remissions in late-stage and advanced tumors of many types, such as NMIBC, MCC, TNBC, pancreatic cancer and head & neck cancer, validating the concept of eliciting immunogenic cell death rather than the tolerogenic cell death induced by current standards of care. A summary of the complete remissions is shown in the image below.



With 2024 approval, the potential for ANKTIVA to be the foundational IL-15 cytokine activating natural killer cells and killer T cells with resultant complete remission even in late-stage advanced tumors across multiple tumor types

ImmunityBio Platforms - The Development of a Universal Therapeutic Cancer Vaccine

Based on the vision of activating the patient's immune system, the company continues its efforts to demonstrate that a universal cancer vaccine that leverages the power of its platforms – backbone ANKTIVA, off-the-shelf and autologous NK-cell-based therapies, adenovirus-vectored delivered vaccines, and other technologies – provide benefit and hope not only for patients with cancer but also for those with a high risk of developing cancer.



Select Clinical Development Program 2025+

The future of immunotherapy appears bright and I continue my quest to drive towards a therapeutic vaccine across multiple tumor types where patients do not suffer the adverse events of high-dose chemotherapy and high-dose radiotherapy. We have made and are targeting multiple submissions to the FDA in 2025 and beyond. In February 2025, the FDA authorized an EAP allowing us to provide rBCG developed by Serum Institute to urologists to address the TICE BCG shortage in all settings where TICE BCG is approved.

In addition, as announced on February 27, 2025, the FDA has granted ImmunityBio RMAT designation for ANKTIVA and PD-L1 t-haNK in combination with standard-of-care chemotherapy/radiotherapy indicated for the reversal of lymphopenia and treatment of multiply relapsed locally advanced or metastatic pancreatic cancer. This RMAT designation follows clinical data of ALC and significant overall survival correlations in QUILT trials across multiple tumor types including third-line or greater metastatic pancreatic cancer, checkpoint relapsed NSCLC, and supportive data from healthy volunteers. The reversal of lymphopenia by ImmunityBio's IL-15 receptor superagonist is consistent with the mechanism of action of ANKTIVA demonstrating proliferation and activation of NK cells, CD4+ T cells, CD8+ T cells, and memory T cells without upregulation of suppressive T reg cells and approved in the ANKTIVA label (approved for the treatment of adult patients with BCG-unresponsive NMIBC with CIS with or without papillary tumors. ImmunityBio intends to submit a BLA for the indication of reversal of lymphopenia in patients receiving standard-of-care chemotherapy and/or radiation and for the treatment of locally advanced or metastatic pancreatic cancer which includes the first-in-class CAR-NK (PD-L1 t-haNK, and to provide data from fully enrolled clinical trials in metastatic pancreatic cancer (QUILT 88 and in checkpoint relapsed NSCLC (QUILT 3055, NSCLC Cohort patients, as well as lymphopenia reversal across multiple tumor types (QUILT 3055, all Cohorts, with supportive data of lymphocyte proliferation in healthy volunteers (QUILT 1004. In addition, ImmunityBio intends to file an EAP for ANKTIVA and PD-L1 t-haNK in combination with standard-of-care chemotherapy/radiotherapy and submit the protocol to the FDA.

ImmunityBio Business, Strategy and Products

Our Business

ImmunityBio is a vertically-integrated commercial stage biotechnology company developing next-generation therapies that bolster the natural immune system to defeat cancers and infectious diseases. The company's range of immunotherapy platforms, alone and together, act to drive an immune response with the goal of creating durable immune memory generating safe protection against disease. We are applying our science and platforms to treating cancers, including the development of potential cancer vaccines, as well as developing immunotherapies and cell therapies that we believe sharply reduce or eliminate the need for standard high-dose chemotherapy. These platforms and their associated product candidates are designed to be more effective, accessible, and easily administered than current standards of care in oncology and infectious diseases.

Our Strategy

We seek to become a leading global immunological therapeutics company by creating next-generation therapies to address serious unmet needs within urologic and other cancers as well as infectious diseases. To achieve this goal, the key elements of our strategy include:

- advancing the commercialization of ANKTIVA as an integral component of immunotherapy combinations, including those with CPIs and cell therapy;
- accelerating product candidates generated from our immunotherapy platforms with registrational intent to address difficult-to-treat oncological and infectious disease indications in large market segments;
- continuously refining our pipeline and investing in high-value discovery, development, and manufacturing capabilities for our next generation product candidates;
- continuing to prospect, license, and acquire technologies to complement and strengthen our platforms and product candidates, both as single agent and combination therapies, in order to optimize responses of the innate and adaptive immune systems to generate cellular memory against multiple tumor types and infectious diseases; and
- cultivating new and expanding existing collaborations for our multi-stage pipeline to reach global scale efficiently.

Our Approved Product – ANKTIVA

Our lead biologic product ANKTIVA is a novel first-in-class IL-15 receptor superagonist antibody-cytokine fusion protein. On April 22, 2024, the FDA approved our product, ANKTIVA with BCG for the treatment of adult patients with BCG-unresponsive NMIBC with CIS with or without papillary tumors (the "approved product"). ANKTIVA was approved with a label indicating an immunological mechanism of action which proliferates and activates NK, CD8+ and memory T cells without the proliferation of immunosuppressive T-reg cells leading to the establishment of memory T cells. We began commercial distribution of our approved product in May 2024.

We believe there is potential for ANKTIVA to become a therapeutic foundation across all phases of treatment, including in adjunctive therapy, to amplify, reactivate or extend the efficacy of standard of care. ANKTIVA is being clinically evaluated in multiple oncology indications. We believe that other oncology indications with registration potential for ANKTIVA include other types of NMIBC (BCG-unresponsive papillary, BCG-naïve CIS and BCG-naïve papillary), lung, colorectal, pancreatic, prostate and ovarian cancers, and GBM and NHL.

Data from multiple clinical trials suggest ANKTIVA has potential to enhance the activity of therapeutic mAbs, including CPIs (e.g., pembrolizumab/Keytruda), across a wide range of tumor types, including lung cancer. Further, ANKTIVA has been observed to increase lymphocyte count in healthy adults, making it a potential therapy to rescue lymphopenia. We believe that the FDA authorization of RMAT designation for ANKTIVA and PD-L1 t-haNK in combination with standard-of-care chemotherapy/ radiotherapy indicated for the reversal of lymphopenia and treatment of multiply relapsed locally advanced or metastatic pancreatic cancer may lead to a potential paradigm change in cancer care. We are also exploring or pursuing several other studies of ANKTIVA in combination with our other product candidates, including in prostate cancer (ANKTIVA in combination with hAd5 PSA), colon cancer (ANKTIVA in combination with hAd5 TriAd), and NHL (ANKTIVA in combination with rituximab). We are also exploring ANKTIVA in infectious diseases, including HIV and long COVID.

Key Catalysts for ANKTIVA

The following is a summary of selected significant developments affecting our business that occurred since the filing of our Quarterly Report dated September 30, 2024 with the SEC on November 12, 2024:

- ANKTIVA received a J-code (J9028) assigned by the CMS in the U.S. for ANKTIVA (Injection, nogapendekin alfa inbakicept-pmln, for intravesical use, 1 microgram), which became effective on January 1, 2025.

- With a permanent J-code awarded in January 2025, our February 2025 ANKTIVA unit sales volume grew 97% over unit sales volume in December 2024 and 67% over unit sales volume in January 2025.

- ANKTIVA is now widely accessible to patients through commercial and government insurance programs (VA, DoD, Medicare). To date, commercial and governmental insurance cover over 240 million lives for ANKTIVA.

- We completed the submission of MAAs for the treatment of patients with BCG-unresponsive NMIBC with CIS with or without papillary tumors for ANKTIVA in combination with BCG to the MHRA in the UK in November 2024 and to the EMA in the EU in December 2024. The MHRA validated and accepted the MAA for review in February 2025, while the EMA accepted the MAA for review in January 2025. We are in continued dialogue for requests for information from both the MHRA and EMA, with the potential for approval in the UK and EU by 2026.

- In collaboration with Serum Institute, and in connection with our exclusive global supply arrangement that we announced during 2024, in February 2025 the FDA authorized an EAP allowing us to provide rBCG developed by Serum Institute to urologists to address the TICE BCG shortage in all settings where TICE BCG is approved, and we are also testing rBCG in an FDA-approved clinical trial in the U.S. Serum Institute's GMP capacity to manufacture large-scale volumes of rBCG, already tested for safety and efficacy in clinical trials in Europe in subjects with NMIBC, aims to address the shortage of TICE BCG, which we believe will help to ensure a reliable supply for patients in need. This initiative underscores our commitment to addressing critical supply issues and expanding the opportunity for patients and physicians to have access to high quality and quantities of BCG to initialize and maintain treatments for bladder cancer, subject to regulatory approvals. We expect to begin shipments of rBCG pursuant to the EAP during the first quarter of 2025.

- In January 2025, we announced a collaboration and supply agreement with BeiGene, Ltd. (to be renamed to BeOne Medicines, Ltd.), a global oncology company, to conduct a confirmatory randomized Phase 3 clinical trial (ResQ201A-NSCLC), combining BeOne's tislelizumab, a PD-1 CPI, and our ANKTIVA (nogapendekin alfa inbakicept-pmln) product. The Phase 3 ResQ201A-NSCLC study aims to confirm the efficacy and safety of combination ANKTIVA plus CPI therapy previously demonstrated in the QUILT 3055 trial and provide evidence of the potential for these two immunotherapeutic agents to improve overall survival in patients with advanced or metastatic NSCLC who have acquired resistance to immune CPI therapy.

- On February 27, 2025, the FDA granted us RMAT designation for ANKTIVA and CAR-NK (PD-L1 t-haNK) in combination with standard-of-care chemotherapy/radiotherapy indicated for the reversal of lymphopenia and treatment of multiply relapsed locally advanced or metastatic pancreatic cancer. This RMAT designation follows clinical data of ALC and significant overall survival correlations in QUILT trials across multiple tumor types including third-line or greater metastatic pancreatic cancer, checkpoint relapsed NSCLC, and supportive data from healthy volunteers. The reversal of lymphopenia by our IL-15 receptor superagonist is consistent with the mechanism of action of ANKTIVA demonstrating proliferation and activation of NK cells, CD4+ T cells, CD8+ T cells, and memory T cells without upregulation of suppressive T-reg cells and approved in the ANKTIVA label (approved for the treatment of adult patients with BCG-unresponsive NMIBC with CIS with or without papillary tumors). We intend to submit a BLA for the indication of reversal of lymphopenia in patients receiving standard of care chemotherapy and/or radiation and for the treatment of locally advanced or metastatic pancreatic cancer which includes the first-in-class CAR-NK (PD-L1 t-haNK), and to provide data from fully enrolled clinical trials in metastatic pancreatic cancer (QUILT 88) and in checkpoint relapsed NSCLC (QUILT 3055, NSCLC Cohort) patients, as well as lymphopenia reversal across multiple tumor types (QUILT 3055, all Cohorts), with supportive data of lymphocyte proliferation in healthy volunteers (QUILT 1004). In addition, we intend to file an EAP for ANKTIVA and PD-L1 t-haNK in combination with standard of care chemotherapy/radiotherapy and to submit the protocol to the FDA.

2025 Platforms and Indications

Our proprietary platforms for the development of biologic products and product candidates include:

Our Next-Generation Platforms	
i.	*Cytokine Fusion Proteins*
	a. ANKTIVA
ii.	*DNA and Vaccine Vectors*
	a. hAd5 (PSA, Brachyury, CEA, MUC1, HPV [E6/E7], neoantigens, nucleocapsid)
iii.	*Cell Therapies*
	a. CD19 t-haNK
	b. PD-L1 t-haNK
	c. M-ceNK (autologous, allogeneic)

Indications (Current Prioritized Studies)	
i.	BCG-Unresponsive NMIBC with CIS (approved)
ii.	BCG-Unresponsive NMIBC Papillary
iii.	BCG-Naïve NMIBC with CIS
iv.	rBCG in NMIBC
v.	Non-Small Cell Lung Cancer
vi.	Pancreatic Cancer
vii.	Chemotherapy Radiation Lymphopenia
viii.	Lynch Syndrome
ix.	Hematological Malignancies (Liquid Tumors)
x.	Colon Cancer
xi.	Glioblastoma Multiforme
xii.	Non-Hodgkin Lymphoma
xiii.	Ovarian Cancer
xiv.	Prostate Cancer
xv.	HIV
xvi.	Universal Nucleocapsid Vaccine
xvii.	Long COVID

Our Pipeline

Our proprietary platforms for the development of biologic products and product candidates include: (i) cytokine fusion proteins, (ii) vaccine vectors, and (iii) cell therapies. As of December 2024, our platforms have generated nine first-in-human therapeutic agents (including one agent approved by the FDA) that are currently or planned to be studied in clinical trials in liquid and solid tumors. The indications in the table above are among the most frequent and lethal cancer types and where there are high failure rates for existing standards of care or no available effective treatment. We are constantly monitoring and prioritizing clinical development based upon the availability of our resources and the efficacy and market developments of our competitors' products and product candidates, among other factors.

Our platforms and their associated approved product and product candidates are designed to attack cancer and infectious pathogens by activating both the innate immune system, including NK cells, dendritic cells, and macrophages, as well as the adaptive immune system comprising B and T cells, in an orchestrated manner. The goal of this potentially best-in-class approach is to generate immunogenic cell death thereby eliminating rogue cells from the body whether they are cancerous or virally-infected. Our ultimate goal is to overcome the limitations of current treatments, such as CPIs, by turning immunologically cold, MHC-deficient tumors into hot tumors, and/or reducing the need for standard high-dose chemotherapy in cancer by employing a coordinated approach to establish "immunological memory" that confers long-term benefit for the patient.

Our Next-Generation Platforms

Cytokine Fusion Proteins

Cytokine fusion proteins, such as ANKTIVA, represent a novel class of biologics that improve immune responses by enhancing the therapeutic potential of cytokines and promoting lymphocyte infiltration at a site of disease. The cytokine interleukin-15 (IL-15) plays a crucial role in the immune system by affecting the development, maintenance, and function of key immune cells—NK and CD8+ killer T cells—that are involved in killing cancer cells. ANKTIVA is a first-in-class IL-15 receptor superagonist IgG1 fusion complex, consisting of an IL-15 mutant (IL-15N72D) fused with an IL-15Rα, which binds with high affinity to IL-15 receptors on NK, CD4+, and CD8+ T cells. This fusion complex of ANKTIVA, which confers stability and longer half-life than recombinant or native IL-15, mimics the natural biological properties of the membrane-bound IL-15Rα, delivering IL-15 by dendritic cells and drives the activation and proliferation of NK cells with the generation of memory killer T cells that have retained immune memory against these tumor clones. By activating NK cells, ANKTIVA overcomes the tumor escape phase of clones resistant to T cells without stimulating immunosuppressive T-reg cells and restores memory T cell activity with resultant prolonged duration of CR. Further, by stimulating the release of interferon-γ, ANKTIVA restores MHC-I expression, making more tumor cells targets for T-cell killing. As evidenced by its ability to increase lymphocyte counts in healthy adults in Phase 1 testing, ANKTIVA also has the potential to rescue lymphopenia, which is associated with poor prognosis in cancer before treatment or as a consequence of chemo- or radiation therapy.

ANKTIVA's mechanisms-of-action make it an ideal 'backbone' for combination therapy with the company's platforms, such as second-generation hAd5 vaccines, off-the-shelf CAR-engineered NK cells, and M-ceNK cells, as well as other therapeutics including BCG, targeted antibodies, and CPIs.

Leveraging our success with ANKTIVA, we are developing multi-functional cytokine fusion proteins targeting TGF-ß, PD-L1, CD16, CD20, and comprising IL-12, IL-15, and IL-21, amongst others, to further enhance NK and T cell activation directed to the TME or virally infected cells and to modulate the systemic and local immune response to accelerate immunogenic cell death.

DNA and Vaccine Vectors

We have developed and/or acquired rights to multiple vaccine delivery technologies for oncology to deliver common TAAs, and neoepitopes (expressed only by cancer cells) and for infectious diseases to target key viruses. These technologies can deliver DNA and protein subunits to induce B and T cell memory through activation of both CD4+ and CD8+ T cells along with antibody (humoral) responses.

Adenovirus is a well-established viral vector that can be utilized as a vaccine platform to stimulate the immune system, however there is risk for a treated person to develop adenovirus immunity. Our second generation hAd5 vector has unique deletions in the early 1, (E1), early 2 (E2b) and early 3 (E3) regions (hAd5 [E1-, E2b-, E3-]), which allows it to be effective in the presence of pre-existing adenovirus immunity and lowers the risk of generating *de novo* vector-directed immunity. We have developed several hAd5 product candidates that have been evaluated in multiple clinical trials as potential vaccines for and treatments of certain cancers and infectious diseases. Importantly, these product candidates have shown an ability to overcome previous adenovirus immunity in preclinical models and in cancer patients. In oncology, we are clinically evaluating hAd5 product candidates in combination with ANKTIVA to yield immunological immunity in colon cancer (hAd5 TAAs CEA, MUC1, Brachyury; collectively the TriAd) and prostate cancer (hAd5 PSA), and as a single agent in HPV-associated cancers (hAd5 TAA [E6/E7]).

Cell Therapies

We believe that we have one of the most comprehensive clinical-stage cell-based platforms in development. Our engineered NK cells have demonstrated the ability to induce cell death in cancers and virally-infected cells through a variety of concurrent mechanisms including innate killing, antibody-mediated killing, and CAR-directed killing.

Off-The-Shelf Targeted High-Affinity NK Cells

NK cells are a type of cytotoxic lymphocyte critical to the innate immune system. NK cells show spontaneous cytolytic activity against cells under stress such as tumor cells and virally-infected cells. After activation, NK cells secrete several cytokines such as interferon-γ (IFN-γ), tumor necrosis factor-α (TNF-α), granulocyte macrophage colony-stimulating factor (GM-CSF), and chemokines that can modulate the function of other innate and adaptive immune cells. Our proprietary NK-92 cytotoxic cell line (also referred to as aNK) was established from a patient with clonal NK-cell lymphoma. aNK cells can be expanded in culture in the presence of cytokines (IL-2, IL-15). Our "off-the-shelf" aNK cell platform has been molecularly engineered in a variety of ways to boost its killing capabilities against cancers and virally-infected cells. Unlike normal NK cells, our aNK cells do not express the key inhibitory receptors that diseased cells often exploit to turn off the killing function of NK cells thereby escaping elimination. Further, we have genetically engineered our aNK cell platform to generate haNK cells engineered to express the high-affinity variant of the Fcγ receptor (FcγRIIIA/CD16a 158V) as well as endoplasmic reticulum-retained IL-2 that bind to antibodies with demonstrated enhanced ADCC-mediated antitumor activity (Jochems 2016). These antibody-targeted haNK cells are designed to directly bind to IgG1-type antibodies, such as avelumab, trastuzumab, cetuximab, and rituximab, with the intention of enhancing the cancer-killing efficacy of these antibodies by boosting the population of competent NK cells that can kill cancer cells through ADCC.

Our most advanced off-the-shelf NK cell platform, CAR-targeted t-haNK cells, enables innovative, bioengineered cell lines that incorporate all the features of our haNK platform together with a CAR, such as PD-L1. Product candidates under this platform have three modes of killing: innate, antibody-mediated, and CAR-directed killing. These product candidates also include one or more additional expression elements such as functional cytokines, chemokines, and trafficking factors. These product candidates are intended to be combined with commercially-available therapeutic antibodies to effectively target either two different epitopes of the same cancer-specific protein or two entirely different cancer-specific proteins. A number of t-haNK cell lines that express CARs have been developed.

Findings from a preclinical study performed in collaboration with the NCI demonstrated our PD-L1 t-haNK cells exert potent antitumor effects against MDSC and overcome T cell escape in multiple types of resistant tumors. The contribution of PD-L1 t-haNK to antitumor efficacy is further evidenced by data reported at the ASCO meeting in June 2022 and updated at ASCO GI in January 2023 from the QUILT 88 trial of patients with advanced pancreatic cancer who were administered PD-L1 t-haNK, and ANKTIVA. The multi-modal therapy resulted in a median overall survival of 6.3 months (95% CI: 5.0, 7.2 months) in patients who had progressed after two prior lines of therapy, more than doubling the historical survival rate.

haNK cells engineered with CARs targeting CD19 have shown to be effective against *in vitro/in vivo* models of lymphoblastic leukemia and lymphoma (Boissel 2013, Muller 2008, Romanski 2016). The CD19 t-haNK cell line combines the engineered enhancements of haNK cells with the expression of a CAR targeting CD19 and thus has potential to demonstrate robust ADCC antitumor activity against cancerous B cells and provide clinical benefit to patients with R/R NHL.

Clinical trials to assess our t-haNK product candidates have been initiated: PD-L1 t-haNK in a Phase 1 trial in TNBC and a Phase 2 trial in pancreatic cancer; and CD19 t-haNK in a Phase 1 trial in R/R B-Cell NHL. In addition, the FDA recently granted us RMAT designation for ANKTIVA and PD-L1 t-haNK in combination with standard-of-care chemotherapy/ radiotherapy indicated for the reversal of lymphopenia and treatment of multiply relapsed locally advanced or metastatic pancreatic cancer.

Autologous and Allogeneic M-ceNK

NK persistence and function can be enhanced with cytokine stimulation. Our M-ceNK cells are generated from lymphocytes collected from donors that are then pre-activated *ex-vivo* by exposure to interleukins -12 (IL-12), -15 (N-803) and -18 (IL-18), which results in differentiation and acquisition of enhanced responses to cytokine re-stimulation. M-ceNK have increased antitumor characteristics, including enhanced IFN-γ production and cytotoxicity against leukemic cell lines. M-ceNK cells are further distinguished by their unique cell-surface marker profile and their highly desirable feature of immune-memory, marked by their pronounced anti-cancer activity for weeks to months in duration, which has made these cells a research focus for more than a decade. We have developed a unique ability to generate a portfolio of distinct M-ceNK cell products through the application of our proprietary technology and cytokines. Also, we can manufacture these cell products for clinical delivery using our proprietary methods and overall expertise in scale manufacturing of NK cell-based products. A Phase 1 first-in-human trial is open and actively enrolling patients to study the M-ceNK platform in solid tumors (QUILT 3076). In addition, M-ceNK is being evaluated in combination with ANKTIVA and gemcitabine in patients with recurrent platinum-resistant high-grade ovarian cancer (ResQ209) and in combination with ANKTIVA and hAd5-PSA in high-risk prostate cancer (ResQ110A-B).

Indications (Current Prioritized Studies)

Bladder Cancer

In the U.S., bladder cancer was the sixth most commonly-diagnosed cancer and the fourth most commonly-diagnosed solid malignancy in men in 2024. The American Cancer Society estimates there will be 84,870 new cases and 17,420 deaths from bladder cancer in 2025. NMIBC represents approximately 75% of all bladder cancers. Radical cystectomy is a treatment to control the disease for unresponsive NMIBC; however, the procedure introduces compromise to the quality of life and additional costs. There is an urgent, unmet need to treat NMIBC and avoid radical cystectomy of the bladder in an attempt to control the disease.

ANKTIVA received *Breakthrough Therapy* and *Fast Track* designations from the FDA for the treatment of BCG-unresponsive NMIBC with CIS (Cohort A) with or without papillary tumors for which we received approval from the FDA in April 2024. ANKTIVA also received *Fast Track* designation for BCG-unresponsive NMIBC papillary and BCG-naïve NMIBC with CIS. The receipt of such designations may not lead to a faster development process or regulatory review and may not increase the likelihood that our product candidates will receive marketing approval.

In our QUILT 3032 trial, as we reported in November 2022 in *NEJM Evidence*, the primary end points were met for both BCG-unresponsive NMIBC with CIS with a CR rate of 71%, and BCG-unresponsive NMIBC papillary with a 12-month disease-free rate of 55%. As presented at ASCO 2022, the combination of BCG plus ANKTIVA (as measured in BCG-unresponsive NMIBC patients, Cohorts A and B combined) was well-tolerated with 1% treatment-related serious adverse events, 0% immune-related serious adverse events, and 100% bladder cancer-specific overall survival at 24 months. Low-grade treatment-related adverse events include dysuria (22%), pollakiuria (20%), hematuria (17%), fatigue (16%), and urgency (12%), and all other treatment-related adverse events were seen at 7% or less. Seminal patents covering intravesical administration of BCG and ANKTIVA were issued providing term coverage until 2035.

BCG-Unresponsive NMIBC with CIS (Cohort A) – QUILT 3032

In our Phase 2/3 open-label multi-center trial of BCG-unresponsive high-grade NMIBC patients with CIS, the patients receive BCG plus ANKTIVA weekly for six consecutive weeks during induction. The patients also receive additional treatment including three weekly maintenance instillations every three months for up to 12 months and then at month 18. Patients with no disease or low-grade Ta disease at months 24, 30, and 36 are eligible for continued BCG plus ANKTIVA (Cohort A) or ANKTIVA alone (Cohort C) treatment (3 weekly instillations), at the principal investigators' discretion.

The primary endpoint of the BCG-unresponsive NMIBC with CIS trial is a CR rate at any time equal to or greater than 30% and the lower bound of the 95% CI must be greater than or equal to 20% for success. CR, or the disappearance of measurable disease in response to treatment, is evaluated at three months or six months following initial administration of BCG plus ANKTIVA (and every three months thereafter until 24 months). This endpoint would be achieved once at least 24 of the 80 patients in the trial achieve a CR.

A data cut-off occurred in January 2022, which provided a median follow-up in Cohort A of approximately 24 months. Data published in *NEJM Evidence* in November 2022 showed a CR in 58 of 82 patients with a 71% CR rate (95% CI: 59.6, 80.3) and a median duration of CR of 26.6 months (95% CI: 9.9, [upper bound not reached]). At 24 months in patients with a CR, the probability of avoiding cystectomy and disease-specific survival was 91.4% and 100%, respectively. Also, at 24 months in all patients in Cohort A, the probability of avoiding cystectomy and of disease-specific survival was 84.1% and 100%, respectively. In December 2024, we provided an update on the full enrollment of 100 patients with BCG-unresponsive NMIBC with CIS as of November 2024 that have been treated with ANKTIVA in combination with BCG, with a 71% CR rate. In these responders, the range of durable response extended to 54 months. This data was submitted to the EMA in an MAA for ANKTIVA in the EU in December 2024.

As part of planned analyses, BCG-unresponsive patients in the QUILT 3032 trial of ANKTIVA plus BCG completed PRO questionnaires, which revealed stability of both mean physical function and global health from baseline to 24 months on-study for those participants who had reached the 24-month assessment. Further, at month 6, Cohort A (CIS disease) patients that achieved a CR reported higher physical function scores than those without a CR (P=0.0659). Summary scores for the NMIBC-specific questionnaire also remained stable. These PROs, taken together with efficacy findings from both the *NEJM Evidence* report and subsequent follow-up, suggest a favorable risk-benefit ratio for the novel therapeutic combination.

In May 2022, we submitted a BLA to the FDA for our product candidate, ANKTIVA in combination with BCG for the treatment of adult patients with BCG-unresponsive NMIBC with CIS with or without papillary tumors. In May 2023, we received a CRL from the FDA, indicating that the FDA had determined it could not approve the original BLA submission in its initial form, citing deficiencies related to the FDA's pre-license inspection of our third-party CMOs, among other items and made recommendations to address the issues raised.

The CRL that we received in response to our initial BLA submission required us to resubmit the BLA to the FDA addressing the issues in the CRL. On April 22, 2024, the FDA approved our product, ANKTIVA with BCG for the treatment of adult patients with BCG-unresponsive NMIBC with CIS with or without papillary tumors. We are required to comply with certain post-marketing commitments, including completion of our QUILT 3032 clinical trial and annual reporting for up to four years, with a final report submission to the FDA by the end of 2029. We began commercial distribution of our approved product in May 2024.

BCG-Unresponsive NMIBC Papillary (Cohort B) – QUILT 3032

In our Phase 2, open-label multi-center trial of BCG-unresponsive high-grade NMIBC papillary patients (Cohort B), the patients are receiving BCG plus ANKTIVA weekly for six consecutive weeks during induction. The patients also receive additional treatment including three weekly maintenance instillations every three months for up to 12 months and then every nine months for up to 24 months. The primary endpoint of the trial is a 12-month disease free rate greater than or equal to 30% and the lower bound of the 95% CI must be greater than or equal to 20% for success. To meet the primary endpoint, 24 out of 80 patients must be disease free at 12 months.

A data cut-off occurred in January 2022, which provided a median follow-up in Cohort B of approximately 21 months. Data published in *NEJM Evidence* in November 2022 showed a 12-month disease-free survival rate of 55% (95% CI: 42.0, 66.8), with median disease-free survival of 19.3 months (95% CI: 7.4, [upper bound not reached]). At the cutoff date 67 of 72 patients, 93.1%, had not progressed to radical cystectomy and the 24-month disease-free survival rate was 97.7%.

We are preparing to submit an sBLA in 2025 for our innovative treatment targeting BCG-unresponsive NMIBC in the papillary indication. This immunotherapy of rescuing BCG with ANKTIVA represents a step towards providing therapeutic options in patients with BCG unresponsive NMIBC in papillary disease who currently have limited treatment choices and face radical total cystectomy (removal of bladder). The addition of the BCG-unresponsive NMIBC papillary indication could expand the potential patient population benefiting from this therapy and may allow patients to avoid the high morbidity and mortality associated with radical total cystectomy.

BCG-Naïve NMIBC with CIS – QUILT 2005

As discussed above, ANKTIVA received *Fast Track* designation from the FDA for the treatment of BCG-naïve NMIBC with CIS. We are currently enrolling patients in our Phase 2b blinded, randomized, two-cohort, open-label, multi-center trial of intravesical BCG plus ANKTIVA vs. BCG alone, in BCG-naïve patients with high-grade NMIBC with CIS (Cohort A) and NMIBC papillary (Cohort B). Planned enrollment for Cohort A (CIS) and Cohort B (papillary) is 366 patients and 230 patients, respectively. As part of our BLA resubmission for ANKTIVA in combination with BCG for the treatment of adult patients with BCG-unresponsive NMIBC with CIS with or without papillary tumors, we provided an update on the long-term follow-up of BCG-naïve patients in QUILT 2005 receiving ANKTIVA plus BCG for CIS± Ta/T1 in the Phase 1b trial, examining the survival of the 9 subjects who entered the trial since 2014. As initially reported in 2021, all 9 patients (100%) achieved a CR, and in an 8-year follow up, the 6 evaluable patients remain disease-free (two were deceased from causes other than bladder cancer and one was lost to follow-up) with bladder preservation over a median survival period of 8.8 years.

As part of our *Breakthrough Therapy* designation submission for BCG-unresponsive NMIBC with CIS with or without papillary tumors described above, the FDA requested an interim analysis of 43 patients in our QUILT 2005 trial which showed an 84% CR rate at nine months in patients receiving ANKTIVA plus BCG. We continue to enroll patients and expect full enrollment in late 2025 to early 2026 with a data readout from the pivotal clinical trial in the second half of 2026. We are targeting a BLA submission to the FDA in late 2026 to early 2027.

NMIBC – Recombinant BCG as Alternative Source of BCG

In May 2024, we announced an exclusive global arrangement with Serum Institute, the world's largest manufacturer of vaccines by number of doses produced, to supply ImmunityBio with rBCG for use exclusively in combination with ANKTIVA, subject to regulatory approvals. We are responsible, in part, for regulatory submissions, clinical trials and commercialization efforts, and our exclusive rights under the arrangement extend to the scope of the FDA's approval obtained by us for Serum Institute's rBCG product in the U.S. Serum Institute's GMP capacity to manufacture large-scale volumes of rBCG, already tested for safety and efficacy in clinical trials in Europe in subjects with NMIBC, aims to address the shortage of TICE BCG, which we believe will help to ensure a reliable supply for patients in need. In February 2025, the FDA authorized an EAP allowing us to provide rBCG developed by Serum Institute to urologists to address the TICE BCG shortage in all settings where the TICE BCG label is approved, and shipments of rBCG pursuant to the EAP are expected to begin during the first quarter of 2025. In addition, we are testing rBCG in an FDA-approved clinical trial (ResQ133A of intravesical rBCG in participants with NMIBC eligible to receive TICE BCG. This initiative underscores our commitment to addressing critical supply issues and expanding the opportunity for patients and physicians to have access to high quality and quantities of BCG to initialize and maintain treatments for bladder cancer, subject to regulatory approvals.

Lung Cancer

According to the American Cancer Society, lung cancer is the second most common cancer in the U.S. In 2025, it is estimated that 226,650 new cases of lung cancer will be diagnosed in the U.S. and 124,730 deaths will be attributed to the disease. NSCLC accounts for about 87% of all lung cancer diagnoses and there are very few successful treatment options for these patients once the cancer spreads beyond the lungs.

The development of CPIs in NSCLC has been revolutionary, doubling the median overall survival in some settings; however, patient response may be short lived, due to late response and/or disease progression after achieving an initial response. As with bladder cancer, ANKTIVA enhances the proliferation and activation of NK and T cells critical for targeting and killing lung cancer cells. There is therefore a strong rationale to evaluate ANKTIVA in addition to a PD-1 or PD-L1 CPI for patients with NSCLC who have relapsed after achieving an initial response to PD-1 or PD-L1 CPI therapy.

Analysis of pooled data from a Phase 1/2 trial conducted from January 2016 to June 2017 in 23 patients and a subsequent investigator-initiated Phase 2 trial conducted by the Medical University of South Carolina, yielded confirmation of activity of the combination of CPIs and ANKTIVA in relapsed NSCLC relative to historical response rates. In 15 patients with PD-L1 greater than 50%, the overall response rate was 38% and the median overall survival rate was 17.1 months. These preliminary findings were favorable relative to the historical response rates seen in this patient population in the first-line setting with CPI therapy.

Non-Small Cell Lung Cancer – QUILT 3055

On the basis of these findings discussed above, we initiated a single-arm Phase 2b multi-cohort basket trial of ANKTIVA and CPI combinations in patients who have previously received treatment with PD-1/PD-L1 immune CPIs per an FDA-approved indication. Patients enrolled in this trial were eligible if actively progressing on CPI therapy. Upon enrollment, patients continued on the same CPI but with the addition of ANKTIVA. Despite progressing on CPI therapy upon entry into the trial, the majority of patients reverted to stable disease and demonstrated durability of stable disease, some extending as long as nine months. Data presented at the ASCO Annual Meeting in 2021 showed that despite the patients' prior progression on CPI therapy alone, upon entry into the trial the majority of patients experienced clinical benefit either as stable disease (49% or a partial response (9%.

Among 140 patients enrolled in QUILT 3055, the common ANKTIVA attributed grade 1 and 2 adverse events included: injection-site reaction (71%, chills (34%, fatigue (27%, pyrexia (24%, flu-like illness (13%, and decreased appetite (10%. A total of 18 grade 3 and 4 adverse events attributed to ANKTIVA have been reported among 16 patients (12% in the trial as of February 2021. All reported grade 3 and 4 adverse events occurred at a frequency of 5% or less; two patients reported increased alanine amino transferase, increased aspartate amino transferase or increased blood alkaline phosphatase, anemia, injection-site reaction, or injection-site pain. All other occurrences of grade 3 or 4 adverse events that the clinical trial site investigators reported as suspected as being due to ANKTIVA include: decreased lymphocyte count; weight loss; influenza-like illness; injection-site pruritus; cellulitis; injection-site cellulitis; sepsis; deep vein thrombosis; hypovolemic shock; colitis; diarrhea; delirium; respiratory failure; and maculopapular rash. Based on this relatively well-tolerated adverse event profile, coupled with NK and CD8+ T cell stimulatory effects, we believe that ANKTIVA has the potential to become a standard in combination with other immunotherapies for multiple indications.

In September 2024, Dr. John Wrangle gave an oral presentation of the updated QUILT 3055 NSCLC pooled data at the World Conference on Lung Cancer, with data through February 2024 from several cohorts of NSCLC patients who have progressed after CPI therapy. These cohorts are:

- Cohort 1a – NSCLC patients with initial response on single-agent CPI therapy and subsequently progressed on or after that therapy.
- Cohort 2 – NSCLC patients having high PD-L1 expression (tumor proportion score ≥50%) and disease progression on a PD-1/PD-L1 CPI after experiencing an initial response when received CPI as a single-agent for first-line treatment.
- Cohort 3 – NSCLC patients with initial response but subsequently relapsed on maintenance PD-1/PD-L1 CPI therapy when initially received CPI therapy in combination with chemotherapy as first-line treatment.
- Cohort 4 – NSCLC patients currently receiving PD-1/PD-L1 CPI therapy that progressed after experiencing stable disease for at least 6 months during previous treatment with PD-1/PD-L1 CPI therapy.

These results showed a median overall survival of 14.1 months in the 86 patients in the pooled analysis. This is in contrast to the overall survival of 6.1 months (Freeman et al. 2020) for patients who received any therapy post-CPI therapy progression or an overall survival of 7.5 months (Brueckl et al. 2021) for patients who received docetaxel plus ramucirumab after initial failure of first-line chemotherapy plus a CPI.

The Phase 2b study demonstrated prolonged overall survival when ANKTIVA was combined with the same CPIs on which patients were progressing, validating the rescue potential of ANKTIVA for T cells and CPIs. The combination of ANKTIVA plus a CPI represents an immunotherapeutic advance for this disease, when compared to the most frequently used chemotherapy docetaxel in this setting, which has an overall survival ranging from 7 to 10 months and which is associated with high toxicities as a chemotherapeutic agent.

Overall survival in checkpoint relapsed patients ranged up to 58 months. The long duration of survival is potentially a result of ANKTIVA's mechanism of action to stimulate and proliferate memory T cells and overcome immune exhaustion or immune escape mediated by MHC-loss in checkpoint relapse via stimulation of NK cells. We plan to submit a BLA in 2025 for second-line and third-line treatment of patients with NSCLC, who are progressing on CPIs.

Non-Small Cell Lung Cancer – ResQ201A

Following a meeting with the FDA, we launched a pivotal, randomized, open-label Phase 3 clinical trial of ANKTIVA plus tislelizumab (anti-PD-1) and docetaxel vs. docetaxel monotherapy in participants with advanced or metastatic NSCLC who have acquired resistance to immune CPI therapy. A total of 462 patients will be enrolled 1:2 either in a control arm or an experimental arm.

- *Control arm:* Docetaxel (standard of care) N=154. Repeated 3-week cycles with docetaxel.
- *Experimental arm:* ANKTIVA, tislelizumab, N=308. Two 3-week cycles of ANKTIVA, tislelizumab plus docetaxel followed by repeated 3-week cycles of ANKTIVA and tislelizumab (no docetaxel).

Participant randomization to either the control or experimental arm will be stratified by geographical region (North America vs. Europe vs. Asia), NSCLC histology (squamous vs. nonsquamous), and actionable genomic alterations.

The primary outcome is the comparison of overall survival between the experimental and the control arms. We expect full enrollment in early 2026 and a data readout in the second half of 2027.

Colorectal Cancer

According to the American Cancer Society, colorectal cancer is the third-leading cause of cancer-related deaths in the U.S. in men and the fourth-leading cause in women, but it is the second most common cause of cancer deaths when numbers for men and women are combined. Colorectal cancer is expected to cause about 52,900 deaths during 2025.

Lynch Syndrome – QUILT 5015 (NCI)

Lynch Syndrome is the most common cause of hereditary colorectal cancer. People with this syndrome harbor mutations in mismatch repair genes that put them at high risk of developing colorectal cancer. Lynch Syndrome causes about 4,300 colorectal cancers per year. These cancers are more likely to develop at earlier ages, often before the age of 50. If someone has Lynch Syndrome, it means that their close relatives (parents, siblings, and children) have a 50% chance of having the mutation that causes it too.

A Phase 2 trial sponsored by the NCI evaluates the ability of ANKTIVA in combination with our TriAd5–a combination of three vaccines targeting TAAs CEA, MUC1, and Brachyury– to reduce the incidence of cancer onset in people with Lynch Syndrome. The trial recently reached full accrual of participants in the first two open-label phases. The randomized controlled portion of the trial is now recruiting with plans to enroll up to 138 participants.

Pancreatic Cancer

According to the American Cancer Society, pancreatic cancer is the third-leading cause of cancer-related deaths in the U.S. in men and the fourth-leading cause in women, and is also the third most common cause of cancer deaths when numbers for men and women are combined. Pancreatic cancer is expected to cause about 52,000 deaths during 2025, with a five-year survival rate for late-stage cases of only 3%.

Advanced Pancreatic Cancer – QUILT 88

Exploratory Phase 1b/2 trials in patients with second-line or greater metastatic pancreatic cancer in which ANKTIVA was combined with off-the-shelf haNK cells, other agents, and SBRT showed encouraging results in patients with advanced disease. The primary endpoints of the Phase 1b and 2 portions of the trials were safety and objective response rate, respectively. In aggregate, 82% of patients (14/17) with advanced pancreatic cancer achieved disease control following combination therapy including ANKTIVA. There were no ANKTIVA-related grade 3 or 4 adverse events reported.

On the basis of these exploratory trials, together with the preclinical findings that PD-L1 t-haNK is as active as haNK + anti-PD-L1 mAbs, we initiated a first-line through third-line pancreatic cancer clinical trial that uses PD-L1 t-haNK as described below:

- *First-line advanced pancreatic cancer (Cohort A)*. Combination of ANKTIVA with low-dose chemotherapy plus SBRT with or without PD-L1 t-haNK vs. gemcitabine/Abraxane® as the standard-of-care control arm in this randomized trial.

- *Second-line advanced pancreatic cancer (Cohort B)*. Combination of ANKTIVA with low-dose chemotherapy plus SBRT + PD-L1 t-haNK vs. 5FU/Onivyde® as the standard-of-care control arm in this randomized trial.

- *Third-line and beyond (Cohort C)*. Combination of ANKTIVA with low-dose chemotherapy plus SBRT + PD-L1 t-haNK in a single arm cohort of this trial with a primary endpoint of overall survival.

In October 2021, we announced that the trial's Cohort C was fully enrolled. Based on the strength of earlier data and the significant unmet medical need, we submitted an amendment to the FDA to increase enrollment in Cohort C. As of January 2023, as reported at ASCO GI, the median overall survival in this highly advanced group of patients (who failed two to six prior lines of treatment) was 5.8 months (95% CI: 4.9, 6.4 months) exceeding the approximately two- to three-month historical median overall survival. Of the 83 patients, 41 (49.4%) had progressed after two prior lines of therapy. Median overall survival in this group was 6.3 months (95% CI: 5.0, 7.2 months), more than doubling the historical overall survival (survival of three months as reported by Manax et al. ASCO GI 2019). In Cohort C, grade 3 or greater treatment-related adverse events included anemia (32%), neutropenia (25%), thrombocytopenia (13%) and fatigue (7%) while all other grade 3 or greater treatment-related adverse events occurred at a frequency of less than 5%.

On February 27, 2025, the FDA granted us RMAT designation for ANKTIVA and CAR-NK (PD-L1 t-haNK in combination with standard-of-care chemotherapy/radiotherapy indicated for the reversal of lymphopenia and treatment of multiply relapsed locally advanced or metastatic pancreatic cancer. We intend to submit a BLA for the indication of reversal of lymphopenia in patients receiving standard-of-care chemotherapy and/or radiation and for the treatment of locally advanced or metastatic pancreatic cancer which includes the first-in-class CAR-NK (PD-L1 t-haNK, and to provide data from fully enrolled clinical trials in metastatic pancreatic cancer (QUILT 88 and in checkpoint relapsed NSCLC (QUILT 3055, NSCLC Cohort patients, as well as lymphopenia reversal across multiple tumor types (QUILT 3055, all Cohorts, with supportive data of lymphocyte proliferation in healthy volunteers (QUILT 1004. There can be no assurance that we will be successful in targeting the indication.

Prostate Cancer

According to the American Cancer Society, one in eight men will be diagnosed with prostate cancer with an estimated 313,780 new diagnoses in 2025. Prostate cancer is the second leading cause of cancer death in men with 35,770 deaths expected in 2025.

hAd5 PSA has been evaluated in combination with related recombinant hAd5-based cancer vaccines (hAd5 Brachyury and hAd5 MUC1 in a Phase 1 study in participants with mCRPC who had not responded to standard therapies (Bilusic 2021. A total of 18 patients with mCRPC were enrolled and received at least one vaccination. A total of 62 vaccinations were given. The vaccine regimen was found to be well tolerable and safe with no DLTs. The most common adverse events were grade 1 or grade 2 and included injection-site reaction (94.4% of participants, flu-like symptoms (58.8%, and fatigue (38.9%. Treatment-related toxicities were uncommon and included grade 3 decreased lymphocyte count (n=2, grade 2 injection-site reaction (n=7, and grade 2 decreased lymphocyte count (n=1. The recommended Phase 2 dose was determined to be 5×10^{11} viral particles per dose. Grade 3 significant adverse events included anemia, dehydration, hypotension, and lung infection. No significant adverse events were related to study treatment.

We believe the combination of ANKTIVA, hAd5 PSA, M-ceNK cells, and standard-of-care in prostate cancer offers a unique opportunity to overcome resistance mediated by more than one mechanism, specifically, T cell exhaustion and human leukocyte antigen modulation. The overall goals of the treatment regimen are to maximize immune cell death and augment and maintain the innate and adaptive immune responses against cancer cells.

High-Risk Prostate Cancer – ResQ110A

We have initiated a clinical trial to evaluate a new immunotherapy combination of ANKTIVA, hAd5 PSA, and M-ceNK in men with high-risk prostate cancer who have not had prostatectomy. Participants will receive immunotherapy pre- and post-surgery. This open-label study will enroll 20 patients and assess primary endpoints of event-free survival and biochemical recurrence-free survival post-surgery immunotherapy.

High-Risk Prostate Cancer – ResQ110B

We have also initiated a clinical trial to evaluate the immunotherapy combination of ANKTIVA, hAd5 PSA, and M-ceNK in men with high-risk prostate cancer who are ineligible for prostate surgery and receiving external beam radiation therapy. This open-label study will enroll 20 patients and deliver the combination regimen prior to and after radiation therapy. Primary outcomes are complete pathologic response after pre-radiation immunotherapy and prostate-specific antigen levels following post-radiation immunotherapy.

Glioblastoma Multiforme

According to the American Association of Neurological Surgeons, GBM is the most common malignant brain tumor accounting for approximately 48% of all primary brain tumors. GBM has a low survival rate of approximately 40% in the first year after diagnosis and only 17% in the second year. In a preclinical study, we evaluated the activity of ANKTIVA alone and in combination with an anti-PD-1 antibody or stereotactic radiosurgery in a murine GL261-luc GBM model and demonstrated that ANKTIVA as a monotherapy or combination therapy with an anti-PD-1 antibody exhibits a robust antitumor immune response resulting in prolonged survival including complete remission in tumor bearing mice. In addition, treatment with ANKTIVA resulted in long-term immune memory against GBM tumor rechallenge.

Recurrent or Progressive GBM – QUILT 3078

A multi-center, open-label Phase 2/3 trial has been initiated to evaluate the safety and efficacy of combination therapy with ANKTIVA, PD-L1 t-haNK, and bevacizumab in patients with recurrent or progressive GBM. In Phase 2, safety of the combination will be assessed prior to Phase 3 wherein participants will be randomized to either combination therapy or bevacizumab monotherapy as the current standard of care.

- *Pilot (Part A).* Enrollment will be initiated with a single-arm study of 10 patients to receive ANKTIVA, PD-L1 t-haNK, and bevacizumab combination therapy. Continued development of the experimental arm in Part B will be based on the overall risk/benefit of the combined treatment regimen observed in Part A.
- *Randomized Comparison of Combination Therapy vs. Bevacizumab Monotherapy (Part B).* Part B will enroll patients to be randomly assigned (1:1) to the experimental arm or to the control arm.

The trial has enrolled patients with plans to enroll up to 20 patients.

Non-Hodgkin Lymphoma

The American Cancer Society estimates that 80,350 people will be diagnosed with NHL and 19,390 deaths will be attributed to the disease in 2025. A Phase 1 trial evaluating ANKTIVA in combination with rituximab, an anti-CD20 mAb therapy, in patients with iNHL, who had relapsed or were refractory after two lines of therapy, was published in *Clinical Cancer Research* in 2021. The combination regimen of ANKTIVA with rituximab was well tolerated with a single reported grade 4 adverse event and no reported grade 5 adverse events. For patients with anti-CD20 mAb sensitive disease, the overall response rate in the SQ cohort was 78% (7 of 9) with 7 of 7 (100%) responses as complete remission.

NHL types can start in B cells or T cells with B cell lymphomas being more common. Most B cell malignancies express high levels of CD19, including the majority of NHLs, such as diffuse large B cell lymphoma, follicular lymphoma, and mantle cell lymphoma. In addition, many leukemias express high levels of CD19, including B cell precursor acute lymphoblastic leukemia, chronic lymphocytic leukemia, and hairy cell leukemia. As such, two CD19-directed CAR-T cell therapeutics are FDA-approved for use in a variety of indications including NHL and ALL. Like T cells, NK cells can be genetically modified to express CARs that recognize tumor-associated cell-surface antigens and mediate specific recognition and lysis of cancer cells. The CD19 t-haNK cell line combines the engineered enhancements of haNK cells with the expression of a CAR targeting CD19 and thus has the potential to demonstrate robust antibody-dependent cellular cytotoxicity antitumor activity against cancerous B cells and provide clinical benefit to patients with relapsed/refractory NHL.

Relapsed/Refractory Non-Hodgkin Lymphoma – QUILT 3092

We have initiated an open-label, Phase 1, first-in-human trial to evaluate the safety of CD19 t-haNK as a single agent and the safety and preliminary efficacy of CD19 t-haNK in combination with rituximab only and in combination with rituximab and ANKTIVA in subjects with relapsed/refractory NHL.

Ovarian Cancer

The American Cancer Society estimates that 20,890 women will be diagnosed with ovarian cancer and 12,730 deaths will be attributed to the disease in 2025. A woman's risk of getting ovarian cancer in her lifetime is about 1 in 91 and her chance of dying from ovarian cancer is about 1 in 143.

Platinum-Resistant Ovarian Cancer – ResQ209

Platinum-based chemotherapy is the standard-of-care for ovarian cancer; however, 20-30% of patients have cancer recurrence following treatment and are considered platinum-resistant. An open-label Phase 2 trial of ANKTIVA plus M-ceNK in patients with platinum-resistant ovarian cancer has been initiated. In this trial, patients with platinum-resistant high-grade ovarian cancer will receive M-ceNK adoptive cell therapy in combination with ANKTIVA and gemcitabine. Participants will undergo mononuclear cell collection for M-ceNK generation, day 8 induction and every 28-day (if M-ceNK are available) maintenance dosing, along with ANKTIVA. Estimated enrollment is 20 participants. Primary endpoints are progression-free survival using RECIST 1.1 criteria, overall survival, overall response rate, duration of response, disease control rate, and CA-125 levels. Safety endpoints are adverse events, treatment-emergent adverse events and significant adverse events, graded using NCI Common Terminology Criteria for Adverse Events Version 5.0.

Other Oncology Indications

In addition to the indications above, findings from completed QUILT studies, including the achievement of complete remissions in late-stage and advanced tumors of many types, such as MCC, TNBC, pancreatic cancer and head & neck cancer, validate the concept of eliciting immunogenic cell death rather than the tolerogenic cell death induced by current standards of care.

In addition to the trials listed above, we are exploring or pursuing several other company-sponsored and investigator-initiated studies of our product candidates including in colon cancer (hAd5 CEA, ANKTIVA), prostate cancer (ANKTIVA, hAd5 PSA), head and neck cancer (ANKTIVA, hAd5 CEA, hAd5 MUC1, hAd5 Brachyury), among others.

Infectious Disease Indications

In addition to the trials listed above in oncology, our approved product and other product candidates are being evaluated in several other company-sponsored and investigator-initiated studies in infectious diseases.

HIV

HIV affects tens of millions of people globally and while ART has increased the survival of infected HIV individuals, there is currently no cure. One strategy for curing HIV is known as the "kick and kill" approach. The "kick" is to induce HIV out of its latent resting state in T cells, revealing infected cells to the immune system, and the "kill" is to eliminate the infected cells via an immune response or immunotherapy. ANKTIVA is a promising molecule to elicit "kick and kill" because of its ability to activate viral transcription in CD4+ T cells ("kick") while strongly activating CD8+ effector memory cells and NK cells important for recognizing and killing HIV infected cells ("kill"), as well as directing these cells to sites of viral reservoirs. ANKTIVA is being evaluated in investigator-initiated trials as a single agent and in combination with broadly neutralizing antibodies to control HIV in persons living with HIV and persons with acute HIV infection.

Active HIV Infection – University of Minnesota, National Institute of Allergy and Infectious Diseases

Based on the hypothesis that CD8+ T cells will migrate to B cell follicles and reduce the frequency of cells with an inducible HIV provirus in HIV-infected individuals treated with ANKTIVA, a Phase 1 proof-of-concept non-randomized, open-label dose-escalation clinical trial sponsored by the University of Minnesota in collaboration with the NIAID was conducted. The primary assessment is the safety of ANKTIVA in ART-suppressed people living with HIV, along with exploratory analysis of effects on the HIV reservoir. In a 2022 report, no significant laboratory adverse events attributable to ANKTIVA were recorded, and ANKTIVA was associated with proliferation and/or activation of CD4+ and CD8+ T cells and NK cells, with a small but significant decrease in the frequency of peripheral blood mononuclear cells with an inducible HIV provirus.

A separate small HIV Cure Phase 1 trial evaluating ANKTIVA in combination with haploidentical NK cells in HIV-infected patients was completed in 2023. Reported data from the study validate the hypothesis that ANKTIVA combined with NK cells has the potential to reduce viral load in people living with HIV, showing a marked decrease in HIV-producing cells in lymph nodes. The trial is complete, and results were published in May 2024. The approach was well tolerated with no unexpected adverse events. A follow-on trial is being planned to further investigate the above regimen in additional patients.

Active HIV Infection – National Institute of Allergy and Infectious Diseases, Rockefeller University

In June 2021, we announced the opening of a Phase 1 clinical trial sponsored by the AIDS Clinical Trials Group and the NIAID (the HIV Cure Study) that will evaluate whether ANKTIVA alone or together with bNAbs can control HIV following interruption of ART. The Phase 1 open-label, randomized trial will enroll 46 people living with HIV whose virus has been suppressed by ART for approximately two years, including at least 30% cisgender women or transgender men. This trial is actively enrolling as of January 2025.

An additional and companion Phase 1 trial utilizing ANKTIVA and 2 different bNAbs sponsored by The Rockefeller University opened in December 2022. This trial completed enrollment as of January 2025.

Acute HIV Infection – Thai Red Cross and the U.S. Military HIV Research Program

In April 2021, we announced the launch of a Phase 2 trial sponsored by the Thai Red Cross and the U.S. Military HIV Research Program. The trial enrolled 14 patients and was designed to investigate the safety, tolerability and immunostimulatory effects of administering ANKTIVA during acute HIV infection. ANKTIVA was administered subcutaneously at weeks zero, three and six (for a total of three doses) and was initiated together with antiretroviral therapy in order to determine if the immunostimulatory effects of ANKTIVA will reduce the amount of HIV present during acute infection. The trial duration for individual participants was approximately 12 weeks. It is hypothesized that ANKTIVA initiated with anti-retroviral therapy during acute HIV infection will not result in complications or additional toxicities compared with anti-retroviral therapy alone and may result in a reduced viral load in these patients by inhibiting early establishment of HIV reservoirs in infected individuals. The trial was recently completed, and data analyses are ongoing.

Other Infectious Diseases

We previously developed COVID-19 vaccine candidates based on our hAd5 platform that delivered DNA for SARS-CoV-2 spike (S) and nucleocapsid (N) proteins that underwent early clinical testing in the U.S. and South Africa. These trials demonstrated the tolerability of the platforms, which elicited no severe adverse events, and provided evidence of effective antigen delivery. We remain interested in forwarding the idea of a universal nucleocapsid vaccine. Studies on long-term immune responses to SARS-CoV-1, a virus very similar to SARS-CoV-2, have shown that T cell responses to the N protein can provide long-term immunity up to at least 11 years after infection. An N-based vaccine would also overcome the problem of the rapid mutation of S, which renders vaccines less effective over time and necessitates continuous re-design. Because of the cross-reactivity to N from SARS-CoV-1 and -2, we believe a ‘pan-SARS-CoV’ vaccine is possible. This strategy is crucial for developing a universal vaccine that can preemptively address the threat of new coronavirus outbreaks, ensuring long-term and wide-ranging immunity.

The U.S. Centers for Disease Control and Prevention have described long COVID as a chronic condition that remains a serious public health concern. Given the consistent observation of altered immune cell persistence and function in persons experiencing symptoms of long COVID, we are exploring the potential value of ANKTIVA and our vaccine candidates in restoring immune cell function in the millions of people at risk for long COVID. Current evidence suggests long COVID may be due, in part, to persistence of SARS-CoV-2 virus in tissues and that both NK and T cell function are aberrant, resulting in persistent inflammation, damage to the blood-brain barrier, and long COVID symptoms. If this model is correct, then ANKTIVA-mediated enhancement of innate and adaptive immune responses against virus replication or residual virus-infected cells across tissues could improve long COVID symptoms.

Manufacturing and Distribution

We have adopted a strategic position to be vertically-integrated and are committed to the goal of developing our products in compliance with the FDA’s GMP standards for large-scale manufacturing, even during Phase 2 clinical trial development. Biological upstream and downstream manufacturing capabilities, with their attendant know-how and regulatory compliance for approval, have long lead times. We have adopted an approach for preparedness to provide our vaccine, immunotherapy, and cell therapy products at a global scale. As such, we have established our own plants and have access to facilities on a global basis.

Our ability to create an efficient manufacturing process and supply chain will be important in enabling us to develop novel therapies. Our strategy is to anticipate the needs of our early-stage research and development initiatives for preclinical and eventual clinical product candidates with a focus on rapid capability to produce at scale fusion proteins, hAd5, protein subunits, toll receptor activators, and NK cell products. We believe members of our management team, many of whom have experience in both nanoparticle commercialization and large-scale injectable drug production, are capable of constructing the processes and commissioning the facilities necessary to meet our development and commercialization goals. For well-known processes, we currently work and plan to continue working with established third-party CMOs to produce drug substance and drug products. In addition, we plan to further enhance our in-house manufacturing capabilities for drug substance, drug products, and labeling and packaging.

Overview of our Manufacturing Model

Our manufacturing capabilities include advanced technological facilities to produce and test various drug substances and drug products. Our experienced operations and quality team focuses on internal manufacturing and testing with a commitment to create robust, high quality, efficient and consistent supply that meets target product profiles. We believe our Phase 1 manufacturing process is designed to efficiently scale-up through all phases of clinical development to commercial manufacturing to drive successful commercialization.

Commercial cGMP Production

On April 22, 2024, the FDA approved our product, ANKTIVA with BCG for the treatment of adult patients with BCG-unresponsive NMIBC with CIS with or without papillary tumors. We have contracted with multiple multi-national biologics manufacturers with several cGMP-compliant facilities in the U.S., Europe and Asia for production of ANKTIVA for commercial sale and for use in our clinical trials. While we believe the overall experience of these multi-national biologics manufacturers is important, the work they perform for us may involve only one of their facilities. We believe the facilities used for our commercial sales and clinical trials have robust process development and validation and quality oversight with high-capacity production suites operating multiple 2,000-20,000L production bioreactors and high-capacity fill lines.

We previously received a CRL from the FDA in May 2023 in response to our initial BLA submission citing deficiencies related in part to the FDA's pre-license inspection of our third party CMOs. We worked with our CMOs to address the issues raised, resubmitted our BLA in October 2023, and the FDA approved ANKTIVA with BCG for the treatment of adult patients with BCG-unresponsive NMIBC with CIS with or without papillary tumors on April 22, 2024.

Clinical Trial GMP Antibody and Fusion Protein Production

We are committed to the goal of establishing a cGMP-compliant multi-platform facility in California, which includes a large space for the production of antibodies and fusion proteins (including ANKTIVA) to treat cancers and infectious diseases. We plan for this facility to include fully integrated biologic upstream and downstream production suites and a quality assurance/ quality control release laboratory for high-capacity antibody and fusion protein production. We may also potentially use CMOs for our fusion protein candidates.

Clinical Trial GMP Adenovirus

We have established other facilities for adenovirus production in multiple sites in California and a site in Colorado for oncology and infectious diseases. We are committed to the goal of complying with cGMP at these facilities. We believe we possess adequate inventory to supply our ongoing adenovirus-related clinical trial activities for the foreseeable future. We may determine to outsource manufacturing to a third-party CMO beyond the clinical phase. These facilities generally have fully-integrated biologic upstream and downstream production suites and quality assurance/quality control release laboratories for high capacity, continuous, or personalized just-in-time vaccine production.

Clinical Trial GMP NK Cell Therapy Production

We have established other facilities for NK cell therapy product production in multiple sites in California for oncology. We are committed to the goal of complying with cGMP at these facilities. One of our sites in California is dedicated to our off-the-shelf product candidates (including PD-L1 t-haNK and CD19), while another is primarily focused on our M-ceNK product candidates, including a training lab for our second-generation offerings. We are in the process of reviewing our expansion efforts for both our t-haNK and M-ceNK manufacturing capacity with the goal to increase our ability to supply our clinical trials and/or EAPs, as applicable.

cGMP ISO Class 5 Manufacturing Facility

On February 14, 2022, we acquired a leasehold interest in the Dunkirk Facility. This facility has construction needs that may require an additional 12 to 18 months to complete in order for it to be used as intended. These construction needs remain as a result of an ongoing dispute with the Dunkirk Facility's general contractor and a stay in resolving the dispute related to Athenex's ongoing bankruptcy proceedings. In addition, and related to the delayed completion of the facility as described above, in November 2024 we received written notice from our landlord alleging non-compliance with the initial employee headcount requirement of our lease for the Dunkirk Facility. While we are seeking to resolve this matter expeditiously, there can be no assurance that we will succeed in doing so, and we may lose access to the Dunkirk Facility. See Item 1A. *"Risk Factors—We are party to a public-private partnership regarding our manufacturing facility in Dunkirk, New York, and if we or our counterparties fail to meet the obligations of those agreements, it could materially impact our development, operations and prospects"* for more information. We believe this facility has the potential to provide us with a state-of-the-art biotech production center that will substantially expand and diversify our existing manufacturing capacity in the U.S. and the ability to scale production associated with certain of our product candidates.

Manufacture of Platform Product Candidates

ImmunityBio's diverse product candidate portfolio and pipeline requires a broad knowledge of various manufacturing and quality assurance methods. We have invested heavily in the processes, systems, and technology to build an extensive range of manufacturing programs spanning various levels of development from IND-enablement through BLA preparation for our other product candidates.

We believe our plan to selectively use third-party CMOs for certain of our assets at various stages, coupled with internal development, will give us assurance that any products will have backup manufacturing options.

Distribution

In connection with the approval of our product, ANKTIVA with BCG for the treatment of adult patients with BCG-unresponsive NMIBC with CIS with or without papillary tumors, by the FDA on April 22, 2024, we engaged a leading third-party logistic provider in a title model to enable commercial distribution. We began commercial distribution of our approved product in May 2024. We have contracted with large specialty distributors and a large specialty pharmacy provider to make our commercial product available across relevant clinics, hospitals, infusion centers, and government entities.

Competition

We face potential competition from many different sources, including major and specialty pharmaceutical and biotechnology companies, academic research institutions, governmental agencies, and public and private research institutions. Our approved product and other product candidates that we successfully develop and commercialize will compete with current therapies and new therapies that may become available in the future. We believe that the key competitive factors affecting the success of our approved product and other product candidates will include efficacy, safety profile, convenience, cost, market access, commercial efforts, competition, and intellectual property protection.

We have focused our efforts on oncology indications, with a primary focus on urology, and secondarily, infectious disease indications that are difficult to treat and with large unmet needs, and we believe our platform will be broadly applicable across multiple tumor types and infections. Based on the breadth and depth of our platforms, we believe our competitors will range from large pharmaceutical companies to emerging novel biotechnology companies.

Oncology

- *Cytokine Fusion Proteins.* This platform primarily competes with large pharmaceutical companies marketing CPIs. However, the potential exists for some of these large pharmaceutical companies to seek collaboration for the combination of ANKTIVA with their marketed CPI. In the context of NMIBC, we currently compete with Ferring Pharmaceuticals and Merck & Co., Inc. (Merck), and may compete with CG Oncology Inc., enGene Holdings Inc., Janssen Pharmaceuticals, Inc. (Janssen)/Johnson & Johnson, and UroGen Pharma, Inc. in the future. We believe this platform will also compete across oncological indications with immunotherapy fusion protein companies developing similar approaches, including Nektar Therapeutics, Neoleukin Therapeutics, Inc., Novartis International AG (Novartis), F. Hoffmann-La Roche AG (Roche), Sanofi, S.A., and Xencor, Inc.

- *DNA and Recombinant Protein Vaccines*. This platform and the associated product candidates will likely compete with other cancer vaccines. Other potential cancer vaccine competitors include Achilles Therapeutics, BioNTech SE (BioNTech), Geneos Therapeutics, Inc., Hangzhou Neoantigen Therapeutics, Inc., Merck, Moderna, Inc. (Moderna), and Roche.

- *Cell Therapies.* This platform's product candidates (t-haNK and M-ceNK) face competition from several companies focused on NK cell-based approaches, including Artiva Biotherapeutics Inc., Catamaran Bio Inc., Century Therapeutics, Inc., Fate Therapeutics, Inc., Gamida Cell, Ltd., INmune Bio Inc., Nkarta Therapeutics, Inc., NKGen Biotech, Inc., and Shoreline Biosciences, Inc.

  In addition, our NK cell product candidates compete with other cell and molecule-based immunotherapy approaches using or targeting NK cells, NKT cells, T cells, macrophages, and dendritic cells. There are currently seven approved CAR-T cell-based treatments marketed by Autolus Therapeutics, plc (Autolus), Bristol-Myers Squibb Company (BMS) (two marketed products), Gilead Sciences, Inc. (Gilead)/Kite Pharma (two marketed products), Janssen/Johnson & Johnson, and Novartis. Additional companies focused on CAR T-related treatment approaches include Allogene Therapeutics, Inc., BMS, Cellectis SA, Celularity, Inc., Gilead, Janssen, Novartis, Pfizer, Inc. (Pfizer), and Poseida Therapeutics, Inc./Roche. There is also one approved TIL therapy from Iovance Biotherapeutics, Inc. Competitor companies focused on other T cell-based approaches include Adaptimmune Ltd. (with an approved TCR-T cell therapy), Adicet Bio, Inc., Autolus, Beam Therapeutics Inc., BioNTech, GlaxoSmithKline plc. (GSK), Sensei Biotherapeutics, Inc., and Senti Biosciences, Inc.

Infectious Diseases

Currently in infectious disease, ANKTIVA is being used in investigational trials primarily focused on HIV and, if approved, will likely compete with companies who have approved therapeutics for HIV, including Gilead, ViiV Healthcare Limited (a joint venture between GSK, Pfizer, and Shionogi, Inc.), Merck, BMS, and Janssen/Johnson & Johnson).

Additionally, we are exploring the potential value of ANKTIVA and our vaccine candidates in restoring immune cell function in the millions of people at risk for long COVID. These efforts face competition from companies that include Pfizer, Moderna, AIM ImmunoTech, Inc., and Laurent Pharmaceuticals and also efforts to expand the label for approved generic medicines for the treatment of long COVID.

Intellectual Property

We strive to protect and enhance the proprietary technology, inventions, and improvements that are commercially important to our business, including seeking, maintaining, and defending patent rights, whether developed internally or licensed from third parties. Our policy is to seek to protect our proprietary position by, among other methods, filing patent applications in the U.S. and in jurisdictions outside of the U.S. related to our proprietary technology, inventions, improvements, and product candidates that are important to the development and implementation of our business. We also rely on trade secrets and know-how relating to our proprietary technology and product candidates, continuing innovation, and in-licensing opportunities to develop, strengthen, and maintain our proprietary position in the field of cancer therapeutics and immunotherapy. We expect to rely on data exclusivity, market exclusivity, patent term adjustment and patent term extensions when available, as well as on regulatory protection afforded through orphan drug designations. Our commercial success will depend in part on our ability to obtain and maintain patent and other proprietary protection for our product candidates, technology, inventions, and improvements; to preserve the confidentiality of our trade secrets; to maintain our licenses to use intellectual property owned by third parties; to defend and enforce our proprietary rights, including our patents; and to operate without infringing, misappropriating or otherwise violating the valid and enforceable patents and other proprietary rights of third parties.

We have developed, acquired, and in-licensed patents and patent applications across platforms as previously described for activated NK and T cells, and memory T cell activation. With respect to activated NK and T cells, we have developed N-803, an N72D variant IL-15 complexed to a dimeric IL-15Ra/Fc fusion protein and with respect to memory T cell activation, we have developed adenoviral immunotherapies expressing TAAs such as CEA, MUC1, and Brachyury.

As of December 31, 2024, we own patents and patent applications related to the development and commercialization of N-803 in the U.S. and jurisdictions outside of the U.S. Our owned patent portfolio is directed to compositions of matter of N-803, methods of use of N-803, and combinations with additional therapeutics. Excluding any patent term adjustment and patent term extension, the issued U.S. patents directed to N-803 are expected to expire from 2028 to 2040. If patents issue from our pending U.S. patent applications, excluding any patent term adjustment and patent term extension, such patents will be expected to expire from 2031 to 2045. For example, these patents and patent applications include claims directed to:

- compositions of matter of N-803;
- uses of N-803 in methods of treating cancers;
- uses of N-803 in treating HIV; and
- combination treatments using N-803 and additional therapeutics.

In June 2024, we submitted applications to the USPTO for the extension of the patent term of several U.S. patents directed to compositions of matter of N-803, methods of use of N-803 and methods of manufacture of N-803. These applications are currently under review by the USPTO and FDA.

As of December 31, 2024, we own, co-own, and in-license patents and patent applications related to the development and commercialization of cell-based therapies in the U.S. and jurisdictions outside of the U.S. Our owned, co-owned, and in-licensed patent portfolio is directed to compositions of matter of NK, haNK, and t-haNK cell lines, methods of use of these cells, and combinations with additional therapeutics. Excluding any patent term adjustment and patent term extension, the issued U.S. patents directed to these cell therapies, methods of use, and combinations with additional therapeutics are expected to expire from 2025 to 2040. If patents issue from our pending U.S. patent applications, excluding any patent term adjustment and patent term extension, such patents will be expected to expire from 2034 to 2042. For example, these patents and patent applications include claims directed to:

- NK cells;
- haNK cells;
- EGFR t-haNK cells;
- CD19 t-haNK cells;
- HER2 t-haNK cells; and
- PD-L1 t-haNK cells.

As of December 31, 2024, we own patents and patent applications related to development and commercialization of multi-functional antibody-based cytokine fusion proteins targeting the IL-12 pathway, the IL-15 pathway, TGF-ß, PD-L1 and CD20 in the U.S. and jurisdictions outside of the U.S. Our owned patent portfolio is directed to compositions of matter and methods of use of these fusion proteins. Excluding any patent term adjustment and patent term extension, the issued U.S. patents directed to these fusion proteins are expected to expire from 2028 to 2039. If patents issue from our pending U.S. patent applications, excluding any patent term adjustment and patent term extension, these patents will be expected to expire from 2028 to 2044. For example, these patents and patent applications include claims directed to fusions of CPI and TAA binding antibodies and binding molecules with IL-15/IL-15Rα/Fc fusion proteins complexes.

As of December 31, 2024, we own patents and patent applications related to development and commercialization of multi-functional cytokine fusion proteins targeting TGF-ß, the IL-15 pathway, the IL-21 pathway, and CD16 in the U.S. and jurisdictions outside of the U.S. Our owned patent portfolio is directed to compositions of matter and methods of use of these fusion proteins. Excluding any patent term adjustment and patent term extension, the issued U.S. patents directed to these fusion proteins are expected to expire from 2039 to 2041. If patents issue from our pending U.S. patent applications, excluding any patent term adjustment and patent term extension, these patents will be expected to expire from 2039 to 2044. For example, these patents and patent applications include claims directed to fusions of human transforming growth factor receptor and/or IL-15 with tissue factor.

As of December 31, 2024, we exclusively own, and co-own with and in-license from the HHS, patents and patent applications related to the development and commercialization of adenovirus-based cancer and viral immunotherapies, in the U.S. and jurisdictions outside of the U.S. Our patent portfolio is directed to compositions of matter of adenovirus and methods of use of adenovirus in treating or preventing cancer and viral diseases. Excluding any patent term adjustment and patent term extension, the issued U.S. patents directed to adenovirus-based cancer and viral immunotherapies are expected to expire from 2028 to 2039. If patents issue from our pending U.S. patent applications, excluding any patent term adjustment and patent term extension, such patents will be expected to expire from 2028 to 2044. For example, these patents and patent applications include claims directed to:

- adenovirus vectors and virus particles comprising TAAs; and
- uses of adenovirus vectors and virus particles in methods of treating cancers.

As of December 31, 2024, we own U.S. patents and pending U.S. patent applications directed to therapeutics for COVID-19. Some of these patent applications are directed to the use of our adenovirus technologies for a COVID-19 vaccine. Excluding any patent term adjustment and patent term extension, the issued U.S. patents directed to therapeutics for COVID-19 are expected to expire in 2040 and 2042. If any patents issue from our pending U.S. patent applications, excluding any patent term adjustment and patent term extension, such patents will be expected to expire in 2040 and 2042.

As of December 31, 2024, we own patents and patent applications related to the development and commercialization of GMP-in-a-Box in the U.S. and jurisdictions outside of the U.S. Our patent portfolio is directed to GMP-in-a-Box. Excluding any patent term adjustment and patent term extension, the issued U.S. patents directed to GMP-in-a-Box are expected to expire from 2030 to 2037. For example, these patents and patent applications include claims directed to methods, bioreactors, and apparatuses for monitoring and culturing cells.

The terms of individual patents extend for varying periods of time, depending upon the date of filing of the patent application, the date of patent issuance, and the legal term of patents in the countries in which they are obtained. Generally, patents issued for applications filed in the U.S. are effective for 20 years from the earliest effective filing date of a non-provisional patent application. The patent term may be adjusted to compensate for delayed patent issuance when such delays are caused by the USPTO or successful appeals against USPTO actions. There is no statutory limit on this patent term adjustment, which is generally the length of any such delays caused by the USPTO. In addition, in certain instances, a patent term can be extended to recapture a portion of the term effectively lost as a result of the FDA regulatory review period. The restoration period cannot be longer than five years, the total patent term, including the restoration period, must not exceed 14 years following FDA approval, only one patent applicable to an approved drug may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. While we are seeking such patent term extensions where applicable, there is no guarantee that the USPTO and/or FDA will agree with our assessment of whether such extensions should be granted, and if granted, the length of such extensions. While we plan to seek such patent term adjustments where applicable, there is no guarantee that the USPTO will agree with our assessment of whether such adjustments should be granted, and if granted, the length of such adjustments. The duration of patents outside of the U.S. varies in accordance with provisions of applicable local law but typically is also 20 years from the earliest effective filing date. However, the actual protection afforded by a patent varies on a product-by-product and country-to-country basis and depends upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory-related extensions, the availability of legal remedies in a particular country, and the validity and enforceability of the patent.

The patent positions of companies like ours are generally uncertain and involve complex legal and factual questions. No consistent policy regarding the scope of claims allowable in patents in the field of immunotherapy has emerged in the U.S. The patent situation outside of the U.S. is even more uncertain. Changes in either the patent laws or their interpretation in the U.S. and other countries may diminish our ability to protect our inventions and enforce our intellectual property rights, and more generally could affect the value of our intellectual property. In particular, our ability to stop third parties from making, using, selling, offering to sell, or importing products that infringe our intellectual property will depend in part on our success in obtaining and enforcing patent claims that cover our technology, inventions, and improvements. With respect to both licensed and owned intellectual property, we cannot be sure that patents will be granted with respect to any current pending patent applications or with respect to any patent applications filed in the future, nor can we be sure that any existing patents or any patents that may be

granted in the future will be commercially useful in protecting our approved product and other product candidates and the methods used to manufacture our approved product and those other product candidates. Moreover, even our issued patents do not guarantee us the right to practice our technology in relation to the commercialization of our approved product and other product candidates. The area of patent and other intellectual property rights in biotechnology is an evolving one with many risks and uncertainties, and third parties may have blocking patents that could be used to prevent us from commercializing our approved product and other product candidates and practicing our technology. Our issued patents and those that may issue in the future may be challenged, invalidated, or circumvented, which could limit our ability to stop competitors from marketing related products or limit the length of the term of patent protection that we may have for our approved product and other product candidates. In addition, the rights granted under any issued patents may not provide us with protection or competitive advantages against competitors with similar technology. Furthermore, our competitors may independently develop similar technologies. For these reasons, we may have competition for our approved product and other product candidates. Moreover, because of the extensive time required for development, testing and regulatory review of a potential product candidate, it is possible that, before any particular product candidate can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any advantage of the patent.

Our registered trademark portfolio currently contains registered trademarks in the U.S. and in foreign jurisdictions and pending trademark applications in the U.S. and in foreign jurisdictions. We may also rely, in some circumstances, on trade secrets to protect our technology. However, trade secrets are difficult to protect. We seek to protect our trade secrets and other proprietary information, in part, by entering into confidentiality agreements with those who have access to our confidential information, including our employees, contractors, consultants, collaborators, and advisors. We also seek to preserve the integrity and confidentiality of our proprietary technology and processes by maintaining physical security of our premises and physical and electronic security of our information technology systems. Although we have confidence in these individuals, organizations, and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or may be independently discovered by competitors. To the extent that our employees, contractors, consultants, collaborators, or advisors use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions. See Item 1A. *"Risk Factors—Risks Related to Intellectual Property"* and Item 3. *"Legal Proceedings"* of this Annual Report for risks related to our proprietary technology, inventions, improvements, and products.

Collaboration and License Agreements

We anticipate that strategic collaborations will continue to be an integral part of our operations, providing opportunities to leverage our partners' expertise and capabilities to gain access to new technologies and further expand the potential of our technologies and product candidates across relevant platforms. We believe we are well positioned to become a leader in immunotherapy due to our broad and vertically-integrated platforms and through complementary strategic partnerships. Agreements shown below have been arranged in alphabetical order.

The following description of certain of our collaboration and license agreements is not a comprehensive listing of all such agreements to which we are a party, and the inclusion of a description of any collaboration or license agreement is not an indication that we consider such agreement(s) to be material to our business and operations as a whole, which is a dynamic and evolving analysis and may change over time.

Collaboration Agreements

National Cancer Institute

The company and its subsidiaries began their relationship with HHS, as represented by the NCI of the NIH in 2015. Pursuant to the CRADAs, the NCI provides scientific staff and other support necessary to conduct research and related activities as described in the CRADAs. During the term of the initial and amended CRADAs, we collaborated with the NCI on the preclinical and clinical development of our proprietary adenovirus technology expressing TAAs for cancer immunotherapy.

In 2021, the CRADA was amended and the research plan was modified to include the preclinical and clinical development of ImmunityBio's proprietary adenovirus platform expressing TAAs, proprietary agent ANKTIVA and derivatives, an antibody-based cytokine fusion protein and derivatives and/or TxM product candidates, proprietary recombinant NK cells and mAbs, proprietary adjuvants, and other proprietary agents owned or controlled by ImmunityBio for cancer immunotherapy. The term of the CRADA was extended through May 2026. Under this agreement, we agreed to pay NCI funding totaling $1.3 million per year, payable in semi-annual installments each year through 2025.

Serum Institute of India Private Limited

In May 2024, we announced an exclusive global arrangement with Serum Institute, the world's largest manufacturer of vaccines by number of doses produced, to supply ImmunityBio with rBCG for use exclusively in combination with our ANKTIVA product, subject to regulatory approvals. We are responsible, in part, for regulatory submissions, clinical trials and commercialization efforts, and our exclusive rights under the arrangement extend to the scope of the FDA's approval obtained by us for Serum Institute's rBCG product in the U.S. Serum Institute's GMP capacity to manufacture large-scale volumes of BCG, already tested for safety and efficacy in clinical trials in Europe in subjects with NMIBC, aims to address the shortage of TICE BCG, which we believe will help to ensure a reliable supply for patients in need. In February 2025, the FDA authorized an EAP allowing us to provide rBCG developed by Serum Institute to urologists to address the TICE BCG shortage in all settings where the TICE BCG label is approved, and shipments of rBCG pursuant to the EAP are expected to begin during the first quarter of 2025. In addition, we are testing rBCG in an FDA-approved clinical trial (ResQ133A) of intravesical rBCG in participants with NMIBC eligible to receive TICE BCG. This initiative underscores our commitment to addressing critical supply issues and expanding the opportunity for patients and physicians to have access to high quality and quantities of BCG to initialize and maintain treatments for bladder cancer, subject to regulatory approvals.

BeiGene, Ltd.

In January 2025, we announced a collaboration and supply agreement with BeiGene, Ltd. (to be renamed to BeOne Medicines, Ltd.), a global oncology company, to conduct a confirmatory randomized Phase 3 clinical trial (ResQ201A-NSCLC), combining BeOne's tislelizumab, a PD-1 CPI, and our ANKTIVA (nogapendekin alfa inbakicept-pmln) product. The Phase 3 ResQ201A-NSCLC study aims to confirm the efficacy and safety of combination ANKTIVA plus CPI therapy previously demonstrated in the QUILT 3055 trial and provide evidence of the potential for these two immunotherapeutic agents to improve overall survival in patients with advanced or metastatic NSCLC who have acquired resistance to immune CPI therapy.

License Agreements

3M IPC License Agreement

We have licensed rights to 3M-052, a synthetic TLR7/8 agonist, 3M-052 formulations and related technology from 3M IPC and its affiliates and AAHI. In November 2021 we obtained nonexclusive rights in the field of SARS-CoV-2 and in June 2022 we modified those rights and expanded the scope of the license to include (1) SARS-CoV-2 and other infectious diseases including malaria, HIV, tuberculosis, hookworm and varicella zoster on an exclusive basis in countries other than LMIC, and (2) oncology applications, when used in combination with our proprietary technology and/or IL-15 receptor superagonists. Adjuvants are either synthetic or naturally occurring molecules that activate TLRs thereby enhancing the humoral and cell-mediated immune response of vaccines. There are 10 human TLRs expressed either on the inside or outside of the immune cell and their function is to recognize foreign substances expressed by pathogens. Once activated, these TLRs stimulate danger signals to the immune cells initiating an immune response. The synthetic imidazoquinolinone 3M-052 is structurally similar to resiquimod. The 3M-052/Alum adjuvant formulation is in Phase 1 trials in the U.S. with an HIV antigen and has been well-tolerated and immunogenic. In consideration for the license, we agreed to make certain periodic license payments, including $2.25 million each year through June 2025. We have also agreed to make payments upon the achievement of certain regulatory milestone events and tiered royalties ranging from the low to high single-digits as a percentage of net sales. Beginning in April 2026, the annual minimum licensing payment is $1.0 million, which can be credited against any royalty payments due under this agreement. We may terminate this license for any reason after providing 3M and AAHI sixty (60) days' written notice.

GlobeImmune, Inc.

In 2020, we entered into an exclusive licensing agreement with GlobeImmune, a consolidated entity of the company, pursuant to which we obtained worldwide, exclusive licenses under certain patents, know-how, and other intellectual property to use, research, develop and commercialize products with GlobeImmune's Tarmogen-based programs and neoepitopes programs in exchange for a license fee for the first two years of the agreement totaling $1.2 million, up to $345.0 million in milestone payments related to the successful completion of clinical and regulatory milestones and up to $240.0 million in total milestone payments based on licensed product net sales milestones, and a royalty on net sales of licensed products, on a product-by-product basis ranging in percentage from the mid-single digits to the mid-teens. We may terminate this agreement, in whole, or on a licensed-product-by-licensed-product and/or country-by-country basis, at any time upon sixty (60) days' written notice to GlobeImmune.

Sanford Health

In 2017, and as amended in November 2021, we entered into a license agreement with Sanford Health pursuant to which we obtained a worldwide, exclusive license under Sanford's applicable patent and know-how rights to use, make, have made, sell, offer to sell, export and import products for all uses and applications of polynucleotides encoding mutant E16 antigen (mutant HPV16 E6 antigen + mutant HPV16 E7 antigen) and the encoded mutant E16 antigen, in exchange for consideration that includes the amount equal to the patent prosecution costs incurred by Sanford for the prosecution of the licensed patent rights, milestone payments payable upon the achievement of certain contractual and regulatory milestones of up to $2.0 million, a low single-digit percentage royalty on net sales of the resulting licensed products, and a low to high-teen percentage share of non-royalty sublicensing revenue. Our obligation to pay royalties continues, on a licensed product-by-licensed product and country-by-country basis, until the date on which such licensed product is no longer covered by a valid claim of a patent licensed pursuant to the agreement in such country. We must use commercially reasonable efforts to develop and commercialize the licensed products. Sanford is responsible for the prosecution and maintenance of the patents licensed pursuant to the agreement. We are required to use commercially reasonable efforts to develop and make available the licensed products, which include achieving certain regulatory objectives within certain specific time periods. We have the first right to enforce the patents licensed pursuant to the agreement, subject to Sanford's ability to exercise such right if we fail to do so. We may terminate this agreement at any time upon 60 days' written notice to Sanford. Sanford may terminate the agreement in the event of an uncured material breach by us.

In June 2023, we filed an IND for QUILT 3100 exploring the use of an hAd5 [E6/E7] construct known as IBRX-042 in a Phase 1 open-label trial to evaluate safety and determine the MTD in subjects with HPV-associated tumors. During the second half of 2023, we received correspondence from the FDA that it was placing the IND on clinical hold and requesting additional toxicology studies. The company submitted a complete response to the hold letter, and the clinical hold was removed in March 2024. The first patient was enrolled in August 2024, satisfying a commercial milestone. Enrollment for the trial continues at three active clinical sites.

Shenzhen Beike Biotechnology Co. Ltd.

In 2014, Altor entered into a license, development and commercialization agreement with Beike, which agreement was amended and restated in 2017, pursuant to which Altor granted to Beike an exclusive license under certain of its intellectual property rights in order to use, research, develop and commercialize products based on ANKTIVA in China for human therapeutic uses, in exchange for consideration that includes up to $195.5 million in total milestone payments based on the successful completion of regulatory and sales milestones for each resulting product, and a royalty on net sales of licensed products, on a product-by-product basis ranging in percentage from the mid-single digits to the mid-teens. Beike's obligation to pay royalties continues, on a licensed product-by-licensed product basis, until the later of (i) the date on which such licensed product is no longer covered by a valid claim of a patent licensed pursuant to the agreement in China and (ii) ten years after the first commercial sale of such licensed product in China. Altor has the sole right to prosecute and maintain the patents licensed pursuant to the agreement. Altor has the first right to enforce the patents licensed pursuant to the agreement, subject to Beike's ability to exercise such right if Altor fails to do so. Altor and Beike each have the right to terminate the agreement in the event of a material breach by the other party. In 2020, we received a Request for Arbitration before the International Chamber of Commerce, International Court of Arbitration, served by Beike asserting breach of contract under our subsidiary Altor's license agreement with them. See Item 3. *"Legal Proceedings"* for more information.

Government Regulation

In the U.S., the FDA regulates biopharmaceuticals under the FD&C Act and the PHSA. Biopharmaceuticals also are subject to other federal, state, and local statutes and regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or post-market may subject an applicant to administrative or judicial sanctions. These sanctions could include, among other actions, the FDA's refusal to approve pending applications, withdrawal of an approval, a clinical hold, untitled or warning letters, product recalls or market withdrawals, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement and civil or criminal penalties. Any FDA or judicial enforcement action could have a material adverse effect on us. Failure to comply with statutory and regulatory requirements subjects a manufacturer to possible legal or regulatory action, including warning letters, the seizure or recall of products, injunctions, consent decrees placing significant restrictions on or suspending manufacturing operations and civil and criminal penalties. CMOs often encounter difficulties involving production yields, quality control and quality assurance, as well as shortages of qualified personnel. Any of these actions or events could have a material impact on the availability of our product candidates.

The FDA and other regulatory authorities at federal, state, and local levels, as well as in foreign countries, extensively regulate, among other things, the research, development, testing, manufacture, quality control, import, export, safety, effectiveness, labeling, packaging, storage, distribution, record keeping, approval, advertising, promotion, marketing, post-approval monitoring, and post-approval reporting of small molecule and biologics such as those we are developing. We, along with third-party contractors, will be required to navigate the various preclinical, clinical, and commercial approval requirements of the governing regulatory agencies of the countries in which we wish to conduct studies or seek approval or licensure of our product candidates. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local, and foreign statutes and regulations require the expenditure of substantial time and financial resources.

The process required by the FDA before biopharmaceutical product candidates may be marketed in the U.S. generally involves the following:

- completion of preclinical laboratory tests and animal studies performed in accordance with the FDA's GLP guidelines;
- submission to the FDA of an IND, which must become effective before clinical trials may begin and must be updated annually or when significant changes are made;
- approval from an independent IRB or ethics committee for each clinical site before the clinical trial is begun;
- performance of adequate and well-controlled human clinical trials to establish the safety, purity, and potency of the proposed biologic product candidate for its intended purpose;
- preparation of and submission to the FDA of a BLA or NDA, after completion of all required clinical trials;
- a determination by the FDA within 60 days of its receipt of a BLA/NDA to file the application for review;
- satisfactory completion of an FDA Advisory Committee review, if applicable;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the proposed product is produced to assess compliance with cGMP and to assure that the facilities, methods, and controls are adequate to preserve the product candidates' continued safety, quality, purity and potency or efficacy, and of selected clinical investigational sites to assess compliance with GCP guidelines;
- FDA review and approval of the BLA or NDA to permit commercial marketing of the product for particular indications for use in the U.S.; and
- compliance with any post-approval requirements, including the potential requirement to implement a REMS, and the potential requirement to conduct post-approval studies.

The testing and approval process requires substantial time, effort, and financial resources, and we cannot be certain that any approvals for our product candidates will be granted on a timely basis, if at all. Prior to beginning the first clinical trial with a product candidate, we must submit an IND to the FDA. An IND is a request for authorization from the FDA to administer an IND product to humans. The central focus of an IND submission is on the general investigational plan and the protocol(s) for clinical trials. The IND also includes results of animal and *in vitro* studies assessing toxicology, pharmacokinetics, pharmacology, and pharmacodynamic characteristics of the product; chemistry, manufacturing, and controls information; and any available human data or literature to support the use of the investigational product. An IND must become effective before human clinical trials begin. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises safety concerns or questions about the proposed clinical trial. In such a case, the IND may be placed on clinical hold, and the IND sponsor and FDA must resolve any outstanding concerns or questions before the clinical trial can begin. Submission of an IND therefore may or may not result in FDA authorization to begin a clinical trial.

When a clinical trial using genetically engineered cells is conducted at, or sponsored by, institutions receiving NIH funding for wild-type DNA research, prior to the submission of an IND to the FDA, a protocol and related documentation is submitted to and the study is registered with the OBA pursuant to the NIH Guidelines. Compliance with the NIH Guidelines is mandatory for investigators at institutions receiving NIH funds for research involving wild-type DNA, and many companies and other institutions not otherwise subject to the NIH Guidelines voluntarily follow them. The NIH is responsible for convening the RAC, a federal advisory committee that discusses protocols that raise novel or particularly important scientific, safety, or ethical considerations at one of its quarterly public meetings. The OBA will notify the FDA of the RAC's decision regarding the necessity for full public review of a protocol. RAC proceedings and reports are posted to the OBA web site and may be accessed by the public. If the FDA allows the IND to proceed, but the RAC decides that full public review of the protocol is warranted, the FDA will request at the completion of its IND review that sponsors delay initiation of the protocol until after completion of the RAC review process.

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCP guidelines, which include the requirement that all research subjects provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. 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. Furthermore, an independent IRB, for each site proposing to conduct the clinical trial, must review and approve the plan for any clinical trial and its informed consent form before the clinical trial begins at that site and must monitor the study until completed. Regulatory authorities, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk or that the trial is unlikely to meet its stated objectives. Some studies also include oversight by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board, which provides authorization for whether or not a study may move forward at designated check points based on access to certain data from the study and may halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy. There are also requirements governing the reporting of ongoing clinical trials and clinical trial results to public registries.

For purposes of BLA or NDA approval, human clinical trials are typically conducted in three sequential phases that may overlap:

- *Phase 1.* The investigational product is initially introduced into healthy human subjects and tested for safety. In the case of some products for severe or life-threatening diseases, the initial human testing is often conducted in patients.
- *Phase 2.* The investigational product is evaluated in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy or potency of the product for specific targeted diseases and to determine dosage tolerance, optimal dosage, and dosing schedule.
- *Phase 3.* Clinical trials are undertaken to further evaluate dosage, clinical efficacy or potency, and safety in an expanded patient population at geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk to benefit ratio of the product and provide an adequate basis for product labeling.
- *Phase 4.* Companies may voluntarily pursue additional clinical trials after a product is approved to gain more information about the product for that approved indication.

In some cases, the FDA may require an additional trial after a product is approved, and these so-called Phase 4 trials may be a condition to approval of the BLA or NDA.

Phase 1, Phase 2, and Phase 3 testing may not be completed successfully within a specified period, if at all, and there can be no assurance that the data collected will support FDA approval or licensure of the product. Concurrently with clinical trials, companies may complete additional animal studies and develop additional information about the biological characteristics of the product candidate and must finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. To help reduce the risk of the introduction of adventitious agents with use of biological products, the PHSA emphasizes the importance of manufacturing control for products whose attributes cannot be precisely defined. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, must develop methods for testing the identity, strength, quality and purity of the final product, or for biologics, the safety, purity and potency. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

BLA/NDA Submission and Review by the FDA

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, nonclinical studies and clinical trials are submitted to the FDA as part of a BLA for a biologic product candidate or an NDA for a small molecule product candidate requesting approval to market the product for one or more indications. Unless agreed to in advance with the FDA, the BLA/NDA must include all data from pertinent preclinical and clinical trials, including negative or ambiguous results, as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls, and proposed labeling, among other things. Data can come from company-sponsored clinical trials intended to test the safety and effectiveness of the use of the product or from a number of alternative sources, including studies initiated by investigators, including government agencies (e.g., NIH). The submission of a BLA/NDA requires payment of a substantial user fee to the FDA, and the sponsor of an approved BLA/NDA is subject to annual product and establishment user fees. These fees typically increase annually. A waiver of user fees may be obtained under certain limited circumstances.

Within 60 days following submission of the application, the FDA reviews a BLA/NDA to determine if it is substantially complete before the agency accepts it for filing. The FDA may refuse to file any BLA or NDA that it deems incomplete or not properly reviewable at the time of submission and may request additional information. In this event, the BLA/NDA must be resubmitted with the additional information. Once a BLA/NDA has been submitted, the FDA's goal is to review the application within ten months after it accepts the application for filing, or, if the application relates to an unmet medical need in a serious or life-threatening indication, the FDA may review the application six months after the FDA accepts the application for filing. The review process is often significantly extended by FDA requests for additional information or clarification. The FDA reviews a BLA/NDA to determine, among other things, whether a product is safe and effective, or safe, pure, and potent for the proposed indication(s) 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 or efficacy. The FDA may convene an advisory committee to provide clinical insight on application review questions. Before approving a BLA/NDA, the FDA will typically inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities comply with cGMP requirements and are adequate to assure consistent production of the product within required specifications. If applicable, FDA regulations also require tissue establishments to register and list their human cells, tissues, and cellular and tissue-based products with the FDA and to evaluate donors through screening and testing. Additionally, before approving a BLA/NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP guidelines. If the FDA determines that the application, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

The testing and approval process requires substantial time, effort, and financial resources, and each may take several years to complete. The FDA may not grant approval on a timely basis, or at all, and we may encounter difficulties or unanticipated costs in our efforts to secure necessary governmental approvals, which could delay or preclude us from marketing our product candidates. After the FDA evaluates a BLA/NDA and conducts 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 CRL. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A CRL indicates that the review cycle of the application is complete, and the application is not ready for approval. A CRL may request additional information or clarification. The FDA may delay or refuse approval of a BLA/NDA if applicable regulatory criteria are not satisfied, require additional testing or information and/or require post-marketing testing and surveillance to monitor safety or efficacy of a product.

If regulatory approval of a product is granted, such approval may entail limitations on the indicated uses for which such product may be marketed. For example, the FDA may approve the BLA/NDA with a REMS plan to mitigate risks, which could include medication guides, physician communication plans, or other restrictions 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. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing regulatory standards is not maintained or if problems occur after the product reaches the marketplace. The FDA may require one or more Phase 4 post-market trials and surveillance 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. In addition, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory approval of our product candidates under development.

A sponsor may seek approval of its product candidate under programs designed to accelerate the FDA's review and approval of new drugs and biological products that meet certain criteria. Specifically, new drugs and biological products are eligible for *Fast Track* designation if they are intended to treat a serious or life-threatening condition and demonstrate the potential to address unmet medical needs for the condition. For a *Fast Track* product, the FDA may consider sections of the BLA/NDA for review on a rolling basis before the complete application is submitted if relevant criteria are met. A *Fast Track*-designated product candidate may also qualify for priority review. Priority review is granted when there is evidence that the proposed product would be a significant improvement in the safety or effectiveness of the treatment, diagnosis, or prevention of a serious condition. If criteria are not met for priority review, the application is subject to the standard FDA review period. Priority review designation does not change the scientific/medical standard for approval or the quality of evidence necessary to support approval.

Under the accelerated approval program, the FDA may approve a BLA/NDA on the basis of either 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. Post-marketing studies or completion of ongoing studies after marketing approval are generally required to verify the product's clinical benefit in relationship to the surrogate endpoint or ultimate outcome in relationship to the clinical benefit. The Food and Drug Omnibus Reform Act made several changes to the FDA's authorities and its regulatory framework, including, among other changes, reforms to the accelerated approval pathway, such as requiring the FDA to specify conditions for post-approval study requirements and setting forth procedures for the FDA to withdraw a product on an expedited basis for non-compliance with post-approval requirements.

In addition, the FDASIA established *Breakthrough Therapy* designation. A sponsor may seek FDA designation of its product candidate as a *Breakthrough Therapy* if the product candidate is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the therapy may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Sponsors may request the FDA to designate *Breakthrough Therapy* at the time of, or any time after, the submission of an IND, but ideally before an end-of-Phase 2 meeting with the FDA. If the FDA designates *Breakthrough Therapy*, it may take appropriate actions to expedite the development and review of the application, which may include holding meetings with the sponsor and the review team throughout the development of the therapy; providing timely advice to, and interactive communication with, the sponsor regarding the development of the product candidate to ensure that the development program to gather the nonclinical and clinical data necessary for approval is as efficient as practicable; involving senior managers and experienced review staff, as appropriate, in a collaborative, cross-disciplinary review; assigning a cross-disciplinary project lead for the FDA review team to facilitate an efficient review of the development program and to serve as a scientific liaison between the review team and the sponsor; and considering alternative clinical trial designs when scientifically appropriate, which may result in smaller or more efficient clinical trials that require less time to complete and may minimize the number of patients exposed to a potentially less efficacious treatment. *Breakthrough Therapy* designation also allows the sponsor to file sections of the BLA/NDA for review on a rolling basis. We may seek designation as a *Breakthrough Therapy* for some or all of our product candidates.

The 21st Century Cures Act established an expedited review program for RMATs, which include cell and gene therapies, therapeutic tissue engineering products, human cell and tissue products, and combination products using any such therapies or products. This program is intended to facilitate efficient development and expedite review of regenerative medicine therapies, which are intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition and qualify for RMAT designation. A sponsor may request that the FDA designate a product candidate as an RMAT concurrently with or at any time after submission of an IND. The FDA has 60 calendar days to determine whether the product candidate meets the criteria, including whether there is preliminary clinical evidence indicating that the product candidate has the potential to address unmet medical needs for a serious or life-threatening disease or condition. A BLA for a product candidate that has received RMAT designation may be eligible for priority review or accelerated approval through use of surrogate or intermediate endpoints reasonably likely to predict long-term clinical benefit, or reliance upon data obtained from a meaningful number of sites. Benefits of RMAT designation also include early interactions with the FDA to discuss any potential surrogate or intermediate endpoint to be used to support accelerated approval. A product candidate with RMAT designation that is granted accelerated approval and is subject to post-approval requirements may fulfill such requirements through the submission of clinical evidence from clinical studies, patient registries, or other sources of real world evidence, such as electronic health records; the collection of larger confirmatory data sets; or post-approval monitoring of all patients treated with such therapy prior to its approval.

Breakthrough Therapy, Fast Track and RMAT designations and priority review do not change the standards for approval. The receipt of such designations may not lead to a faster development process or regulatory review and may not increase the likelihood that our product candidates will receive marketing approval.

In addition, the PREA requires a sponsor to conduct pediatric clinical trials for certain drugs and biological products, for a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration. Under PREA, original NDAs/BLAs and 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 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 product candidate 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, keeps a deferral current or fails to submit a request for approval of a pediatric formulation.

Orphan Drugs

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition, defined as a disease or condition with a patient population of fewer than 200,000 individuals in the U.S., or a patient population greater than 200,000 individuals in the U.S. and when there is no reasonable expectation that the cost of developing and making available the drug or biologic in the U.S. will be recovered from sales in the U.S. for that drug or biologic. Orphan drug designation must be requested before submitting a BLA or NDA. After the FDA grants orphan drug designation, the generic identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA.

If a product that has orphan drug designation subsequently receives the first FDA approval for a particular active ingredient for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications, including a full BLA or NDA, to market the same biologic or drug product for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity or if the FDA finds that the holder of the orphan drug exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the drug was designated. Orphan drug exclusivity does not prevent the FDA from approving a different drug or biologic for the same disease or condition, or the same drug or biologic for a different disease or condition. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the BLA application user fee.

A designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. In addition, orphan drug exclusive marketing rights in the U.S. may be lost 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.

Post-Approval Requirements

Any products manufactured or distributed by us pursuant to FDA approval 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, distribution, and advertising and promotion of the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing, annual user fee requirements for any marketed products and the establishments at which such products are manufactured, as well as new application fees for supplemental applications with clinical data. Biopharmaceutical manufacturers and their subcontractors 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 cGMP, which impose certain procedural and documentation requirements upon us and any third-party manufacturers that we may decide to use. Changes to the manufacturing process are strictly regulated and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting requirements upon us, and any third-party manufacturers, that we may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance. We cannot be certain that we or our present or future suppliers will be able to comply with cGMP regulations and other FDA regulatory requirements. If our present or future suppliers are not able to comply with these requirements, the FDA may, among other things, halt our clinical trials, require us to recall a product from distribution, or withdraw approval of the BLA or NDA.

In the U.S., once a drug is approved, its manufacture is subject to comprehensive and continuing regulation by the FDA. FDA regulations require that drugs be manufactured in specific facilities per the BLA or NDA approval and in accordance with cGMP. Drug 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 cGMP and other laws. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance. These regulations also impose certain organizational, procedural, and documentation requirements with respect to manufacturing and quality assurance activities. BLA or NDA holders using CMOs, laboratories or packagers are responsible for the selection and monitoring of qualified firms, and, in certain circumstances, qualified suppliers to these firms. These firms and, where applicable, their suppliers are subject to inspections by the FDA at any time, and the discovery of violative conditions, including failure to conform to cGMP, could result in enforcement actions that interrupt the operation of any such facilities or the ability to distribute drugs manufactured, processed, or tested by them.

Future FDA and state inspections may identify compliance issues at our facilities or at the facilities of CMOs that may disrupt production or distribution or require substantial resources to correct. In addition, discovery of previously unknown problems with a product or the failure to comply with applicable requirements may result in restrictions on a product, manufacturer, or holder of an approved BLA or NDA, including withdrawal or recall of the product from the market or other voluntary, FDA-initiated or judicial action that could delay or prohibit further marketing.

Post-Marketing Requirements

Following approval of a new drug, a biopharmaceutical company and the approved drug are subject to continuing regulation by the FDA, including, among other things, establishment registration and drug listing, monitoring and recordkeeping activities, reporting to the applicable regulatory authorities of adverse experiences with the drug, providing the regulatory authorities with updated safety and efficacy information, drug sampling and distribution requirements, and complying with promotion and advertising requirements, which include, among others, standards for direct-to-consumer advertising, restrictions on promoting drugs for uses or in patient populations that are not described in the drug's approved labeling, limitations on industry-sponsored scientific and educational activities, and requirements for promotional activities involving the internet.

In the U.S., once a drug is approved, its manufacture is subject to comprehensive and continuing regulation by the FDA. FDA regulations require that drugs be manufactured in specific facilities per the NDA approval and in accordance with cGMP. We rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of its drugs in accordance with cGMP regulations. cGMP regulations require among other things, quality control and quality assurance as well as the corresponding maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP.

Drug 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 cGMP and other laws. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance. These regulations also impose certain organizational, procedural, and documentation requirements with respect to manufacturing and quality assurance activities. NDA holders using CMOs, laboratories or packagers are responsible for the selection and monitoring of qualified firms, and, in certain circumstances, qualified suppliers to these firms. These firms and, where applicable, their suppliers are subject to inspections by the FDA at any time, and the discovery of violative conditions, including failure to conform to cGMP, could result in enforcement actions that interrupt the operation of any such facilities or the ability to distribute drugs manufactured, processed, or tested by them. Discovery of problems with a drug after approval may result in restrictions on a drug, manufacturer, or holder of an approved NDA, including, among other things, recall or withdrawal of the drug from the market, and may require substantial resources to correct.

The FDA may also require post-approval testing, sometimes referred to as Phase 4 testing, risk minimization action plans, and post-marketing surveillance to monitor the effects of an approved drug or place conditions on an approval that could restrict the distribution or use of the drug. The FDA may withdraw 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 post-market studies or clinical trials to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

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

The FDA closely regulates the marketing, labeling, advertising and promotion of biological or drug products. A company can make only those claims relating to safety and efficacy, purity and potency 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. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties, and exclusion from participation in governmental health programs, like Medicare and Medicaid. Physicians may prescribe legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties. 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. The federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined companies from engaging in off-label promotion. The FDA and other regulatory agencies have also required that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. However, companies may share truthful and not misleading information that is otherwise consistent with a product's FDA-approved labelling. Modifications or enhancements to the drug or its labeling or changes of the site or process of manufacture are often subject to the approval of the FDA and other regulators, which may or may not be received or may result in a lengthy review process.

Prescription drug advertising is subject to federal, state, and foreign regulations. In the U.S., the FDA regulates prescription drug promotion, including direct-to-consumer advertising. Prescription drug promotional materials must be submitted to the FDA in conjunction with their first use. Any distribution of prescription drugs and pharmaceutical samples must comply with the U.S. PDMA, a part of the FD&C Act. The DSCSA, enacted in 2013, aims to build an electronic system to identify and trace certain prescription drugs distributed in the U.S. The DSCSA mandates phased-in and resource-intensive obligations for pharmaceutical manufacturers, wholesale distributors, and dispensers. The law's requirements include the quarantine and prompt investigation of a suspect product to determine if it is illegitimate and notifying trading partners and the FDA of any illegitimate product. Drug manufacturers and their collaborators are also required to place a unique product identifier on prescription drug packages.

Premarket Clearance and Approval Requirements for Medical Devices

Each medical device we seek to commercially distribute in the U.S., including our bioreactors, will require a prior 510(k) clearance, unless it has received a PMA from the FDA. Generally, if a new device has a predicate that is already on the market under a 510(k) clearance, the FDA will allow that new device to be marketed under a 510(k) clearance; otherwise, a PMA is required. Medical devices are classified into one of three classes: Class 1, Class 2, or Class 3, depending on the degree of risk associated with each medical device and the extent of control needed to provide reasonable assurance of safety and effectiveness. Class 1 devices are deemed to be low risk and are subject to the general controls of the FD&C Act, such as provisions that relate to: adulteration; misbranding; registration and listing; notification, including repair, replacement, or refund; records and reports; and good manufacturing practices. Most Class 1 devices are classified as exempt from premarket notification under section

510(k) of the FD&C Act and therefore may be commercially distributed without obtaining 510(k) clearance from the FDA. Class 2 devices are subject to both general controls and special controls to provide reasonable assurance of safety and effectiveness. Special controls include performance standards, post market surveillance, patient registries and guidance documents. A manufacturer may be required to submit to the FDA a premarket notification requesting permission to commercially distribute some Class 2 devices. Devices deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices, or devices deemed not substantially equivalent to a previously cleared 510(k) device, are placed in Class 3. A Class 3 device cannot be marketed in the U.S. unless the FDA approves the device after submission of a PMA. However, there are some Class 3 devices for which the FDA has not yet called for a PMA. For these devices, the manufacturer must submit a premarket notification and obtain 510(k) clearance in orders to commercially distribute these devices. The FDA can also impose sales, marketing, or other restrictions on devices in order to ensure that they are used in a safe and effective manner.

510(k) Clearance Pathway

When a 510(k) clearance is required, we must submit a premarket notification to the FDA demonstrating that our proposed device is substantially equivalent to a predicate device, which is a previously cleared and legally marketed 510(k) device or a device that was in commercial distribution before May 28, 1976. By regulation, a premarket notification must be submitted to the FDA at least 90 days before we intend to distribute a device. As a practical matter, clearance often takes significantly longer. To demonstrate substantial equivalence, the manufacturer must show that the proposed device has the same intended use as the predicate device, and it either has the same technological characteristics, or different technological characteristics and the information in the premarket notification demonstrates that the device is equally safe and effective and does not raise different questions of safety and effectiveness. The FDA may require further information, including clinical data, to make a determination regarding substantial equivalence. If the FDA determines that the device, or its intended use, is not substantially equivalent to a previously cleared device or use, the FDA will place the device into Class 3.

There are three types of 510(k)s: traditional; special; and abbreviated. Special 510(k)s are for devices that are modified, and the modification needs a new 510(k) but does not affect the intended use or alter the fundamental scientific technology of the device. Abbreviated 510(k)s are for devices that conform to a recognized standard. The special and abbreviated 510(k)s are intended to streamline review, and the FDA intends to process special 510(k)s within 30 days of receipt.

De Novo Classification

Medical device types that the FDA has not previously classified as Class 1, 2 or 3 are automatically classified into Class 3 regardless of the level of risk they pose. The Food and Drug Administration Modernization Act of 1997 established a new route to market for low to moderate risk medical devices that are automatically placed into Class 3 due to the absence of a predicate device, called the Request for Evaluation of Automatic Class 3 Designation (or the *De Novo* Classification Process).

This procedure allows a manufacturer whose novel device is automatically classified into Class 3 to request down-classification of its medical device into Class 1 or Class 2 on the basis that the device presents low or moderate risk, rather than requiring the submission and approval of a PMA application. Prior to the enactment of the FDASIA, a medical device could only be eligible for *De Novo* classification if the manufacturer first submitted a 510(k) premarket notification and received a determination from the FDA that the device was not substantially equivalent. The FDASIA streamlined the *De Novo* classification pathway by permitting manufacturers to request *De Novo* classification directly without first submitting a 510(k) premarket notification to the FDA and receiving a not substantially equivalent determination. Under the FDASIA, the FDA is required to classify the device within 120 days following receipt of the *De Novo* application. If the manufacturer seeks reclassification into Class 2, the manufacturer must include a draft proposal for special controls that are necessary to provide a reasonable assurance of the safety and effectiveness of the medical device. In addition, the FDA may reject the reclassification petition if it identifies a legally marketed predicate device that would be appropriate for a 510(k) or determines that the device is not low to moderate risk or that general controls would be inadequate to control the risks and special controls cannot be developed.

Premarket Approval Pathway

A PMA application must be submitted to the FDA for Class 3 devices for which the FDA has required a PMA. The PMA application process is much more demanding than the 510(k) premarket notification process. A PMA application must be supported by extensive data, including but not limited to technical, preclinical, clinical trials, manufacturing and labeling to demonstrate to the FDA’s satisfaction reasonable evidence of safety and effectiveness of the device.

After a PMA application is submitted, the FDA has 45 days to determine whether the application is sufficiently complete to permit a substantive review and thus whether the FDA will file the application for review. The FDA has 180 days to review a filed PMA application, although the review of an application generally occurs over a significantly longer period of time and can take up to several years. During this review period, the FDA may request additional information or clarification of the information already provided. Also, an advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device.

Although the FDA is not bound by the advisory panel decision, the panel's recommendations are important to the FDA's overall decision-making process. In addition, the FDA may conduct a preapproval inspection of the manufacturing facility to ensure compliance with the QSR. The agency also may inspect one or more clinical sites to assure compliance with FDA's regulations.

Upon completion of the PMA review, the FDA may: (i) approve the PMA application which authorizes commercial marketing with specific prescribing information for one or more indications, which can be more limited than those originally sought; (ii) issue an approvable letter which indicates the FDA's belief that the PMA application is approvable and states what additional information the FDA requires or the post-approval commitments that must be agreed to prior to approval; (iii) issue a not approvable letter which outlines steps required for approval, but which are typically more onerous than those in an approvable letter, and may require additional clinical trials that are often expensive and time consuming and can delay approval for months or even years; or (iv) deny the application. If the FDA issues an approvable or not approvable letter, the applicant has 180 days to respond, after which the FDA's review clock is reset.

Clinical trials are almost always required to support PMA and are sometimes required for 510(k) clearance. In the U.S., for significant risk devices, these trials require submission of an application for an IDE to the FDA. The IDE application must be supported by appropriate data, such as animal and laboratory testing results, showing it is safe to test the device in humans and that the testing protocol is scientifically sound. The IDE must be approved in advance by the FDA for a specific number of patients at specified trial sites. During the trial, the sponsor must comply with the FDA's IDE requirements for investigator selection, trial monitoring, reporting and recordkeeping. The investigators must obtain patient informed consent, rigorously follow the investigational plan, and trial protocol, control the disposition of investigational devices and comply with all reporting and recordkeeping requirements. Clinical trials for significant risk devices may not begin until the IDE application is approved by the FDA and the appropriate IRBs at the clinical trial sites. An IRB is an appropriately constituted group that has been formally designated to review and monitor medical research involving subjects and which has the authority to approve, require modifications in, or disapprove research to protect the rights, safety, and welfare of human research subjects. A non-significant risk device does not require FDA approval of an IDE; however, the clinical trial must still be conducted in compliance with various requirements of FDA's IDE regulations and be approved by an IRB at the clinical trial sites. The FDA or the IRB at each site at which a clinical trial is being performed may withdraw approval of a clinical trial at any time for various reasons, including a belief that the risks to study subjects outweigh the benefits or a failure to comply with FDA or IRB requirements. Even if a trial is completed, the results of clinical testing may not demonstrate the safety and effectiveness of the device, may be equivocal or may otherwise not be sufficient to obtain approval or clearance of the product.

Sponsors of clinical trials of devices are required to register with clinical trials.gov, a public database of clinical trial information. Information related to the device, patient population, phase of investigation, study sites and investigators and other aspects of the clinical trial is made public as part of the registration.

Ongoing Medical Device Regulation by the FDA

Even after a device receives clearance or approval and is placed on the market, numerous regulatory requirements apply. These include:

- establishment registration and device listing;
- the QSR, which requires manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation, and other quality assurance procedures during all aspects of the manufacturing process;
- labeling regulations and the FDA prohibitions against the promotion of products for uncleared, unapproved or off-label uses and other requirements related to promotional activities;

- medical device reporting regulations, which require that manufactures report to the FDA if their device may have caused or contributed to a death or serious injury, or if their device malfunctioned and the device or a similar device marketed by the manufacturer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur;
- corrections and removal reporting regulations, which require that manufacturers report to the FDA field corrections or removals if undertaken to reduce a risk to health posed by a device or to remedy a violation of the FD&C Act that may present a risk to health; and
- post market surveillance regulations, which apply to certain Class 2 or 3 devices when necessary to protect the public health or to provide additional safety and effectiveness data for the device.

After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, will require a new clearance or possibly a PMA. The FDA requires each manufacturer to make this determination initially, but the FDA can review any such decision and can disagree with a manufacturer's determination. If the FDA disagrees with the determination not to seek a new 510(k) clearance, the FDA may retroactively require the manufacturer to seek 510(k) clearance or possibly a PMA. The FDA could also require the manufacturer to cease marketing and distribution and/or recall the modified device until 510(k) clearance or PMA is obtained. Also, in these circumstances, the manufacturer may be subject to significant regulatory fines and penalties.

Some changes to an approved PMA device, including changes in indications, labeling or manufacturing processes or facilities, require submission and FDA approval of a new PMA application or PMA supplement, as appropriate, before the change can be implemented. Supplements to a PMA application often require the submission of the same type of information required for an original PMA application, except that the supplement is generally limited to that information needed to support the proposed change from the device covered by the original PMA. The FDA uses the same procedures and actions in reviewing PMA supplements as it does in reviewing original PMA applications.

FDA regulations require us to register as a medical device manufacturer with the FDA. Additionally, some states require us to register as a medical device manufacturer within the state. Because of this, the FDA and similar state agencies may inspect us on a routine basis for compliance with the QSR. In February 2024, the FDA issued a final rule replacing the QSR with the QMSR, which incorporates by reference the quality management system requirements of ISO 13485:2016. The FDA has stated that the standards contained in ISO 13485:2016 are substantially similar to those set forth in the existing QSR. This final rule does not go into effect until February 2026. These regulations require that the manufacturer maintain proper documentation in a prescribed manner with respect to manufacturing, testing and control activities. Further, the FDA requires medical device manufacturers to comply with various FDA regulations regarding labeling.

Failure by us or by our suppliers to comply with applicable regulatory requirements can result in enforcement action by the FDA or state authorities, which may include any of the following sanctions:

- warning or untitled letters, fines, injunctions, consent decrees and civil penalties;
- customer notifications, voluntary or mandatory recall or seizure of our medical device product candidates;
- operating restrictions, partial suspension, or total shutdown of production;
- delay in processing submissions or applications for new products or modifications to existing products;
- withdrawing approvals that have already been granted; and
- criminal prosecution.

The Medical Device Reporting laws and regulations require medical device manufacturers to provide information to the FDA when they receive or otherwise become aware of information that reasonably suggests the device may have caused or contributed to a death or serious injury as well as a device malfunction that likely would cause or contribute to death or serious injury if the malfunction were to recur. In addition, the FDA prohibits an approved device from being marketed for off-label use. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability, including substantial monetary penalties and criminal prosecution.

Newly discovered or developed safety or effectiveness data may require changes to a product's labeling, including the addition of new warnings and contraindications, and also may require the implementation of other risk management measures. Also, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory clearance or approval of our medical device product candidates under development. Medical device manufacturers are also subject to other federal, state, and local laws and regulations relating to safe working conditions, and laboratory and manufacturing practices.

Other Healthcare Laws and Compliance Requirements

Manufacturing, sales, promotion, and other activities following drug approval are also subject to regulation by numerous regulatory authorities in addition to the FDA, including, in the U.S., CMS, other divisions of HHS, the Drug Enforcement Administration for controlled substances, the Consumer Product Safety Commission, the FTC, Occupational Safety and Health Administration, the Environmental Protection Agency, and state and local governments. In the U.S., sales, marketing, and scientific/educational programs must also comply with state and federal fraud and abuse laws. Pricing and rebate programs must comply with the Medicaid rebate requirements of the U.S. Omnibus Budget Reconciliation Act of 1990 and more recent requirements in the Patient Protection and Affordable Care Act as amended by the ACA. If drugs are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. The handling of any controlled substances must comply with the U.S. Controlled Substances Act and Controlled Substances Import and Export Act. Drugs must meet applicable child-resistant packaging requirements under the U.S. Poison Prevention Packaging Act. Manufacturing, sales, promotion, and other activities are also potentially subject to federal and state consumer protection and unfair competition laws.

We are subject to numerous foreign, federal, state, and local environmental, health, and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment, and disposal of hazardous materials and wastes. In addition, our leasing and operation of real property may subject us to liability pursuant to certain U.S. environmental laws and regulations, under which current or previous owners or operators of real property and entities that disposed or arranged for the disposal of hazardous substances may be held strictly, jointly, and severally liable for the cost of investigating or remediating contamination caused by hazardous substance releases, even if they did not know of and were not responsible for the releases.

The distribution of pharmaceutical drugs is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage, and security requirements intended to prevent the unauthorized sale of pharmaceutical drugs. The failure to comply with regulatory requirements subjects firms to possible legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can result in criminal prosecution, fines, or other penalties, injunctions, voluntary recall, or seizure of drugs, total or partial suspension of production, denial or withdrawal of product approvals, or refusal to allow a firm to enter into supply contracts, including government contracts. In addition, even if a firm complies with FDA and other requirements, new information regarding the safety or efficacy of a product could lead the FDA to modify or withdraw product approval. Prohibitions or restrictions on sales or withdrawal of future products marketed by us could materially affect our business in an adverse way.

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

Our sales, promotion, medical education, clinical research, and other activities following product approval will be subject to regulation by numerous regulatory and law enforcement authorities in the U.S. in addition to the FDA, including potentially the FTC, the Department of Justice, the CMS, other divisions of HHS and state and local governments. Our promotional and scientific/educational programs must comply with the AKS, the FCA, physician payment transparency laws, privacy laws, security laws, and additional federal and state laws similar to the foregoing. If drugs are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. Drugs must meet applicable child-resistant packaging requirements under the U.S. Poison Prevention Packaging Act. Manufacturing, sales, promotion, and other activities are also potentially subject to federal and state consumer protection and unfair competition laws. Changes in regulations, statutes, or the interpretation of existing regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements; (ii) additions or modifications to product labeling; (iii) the recall or discontinuation of our products; or (iv) additional record-keeping requirements. If any such changes were imposed, they could adversely affect the operation of our business.

The AKS prohibits, among other things, the knowing and willing, direct or indirect offer, receipt, solicitation, or payment of remuneration in exchange for or to induce the referral of patients, including the purchase, order or lease of any good, facility, item or service that would be paid for in whole or part by Medicare, Medicaid or other federal health care programs. Remuneration has been broadly defined to include anything of value, including cash, improper discounts, and free or reduced-price items and services. The AKS has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, formulary managers, and beneficiaries on the other. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exceptions and safe harbors are drawn narrowly. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the AKS. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all its facts and circumstances. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the AKS has been violated. The government has enforced the AKS to reach large settlements with healthcare companies based on sham research or consulting and other financial arrangements with physicians. Further, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the AKS constitutes a false or fraudulent claim for purposes of the FCA. Many states have similar laws that apply to their state health care programs, as well as private payors.

Federal false claims and false statement laws, including the FCA, impose liability on persons or entities that, among other things, knowingly present or cause to be presented claims that are false or fraudulent or not provided as claimed for payment or approval by a federal health care program. The FCA has been used to prosecute people or entities that cause the submission of claims for payment that are inaccurate or fraudulent, by, for example, providing inaccurate billing or coding information to customers, promoting a product off-label, submitting claims for services not provided as claimed, or submitting claims for services that were provided but not medically necessary. Actions under the FCA may be brought by the Attorney General, or as a qui tam action by a private individual, in the name of the government. Violations of the FCA can result in significant monetary penalties and treble damages. The federal government is using the FCA, and the accompanying threat of significant liability, in its investigation and prosecution of pharmaceutical and biotechnology companies throughout the country, for example, in connection with the promotion of products for unapproved uses and other illegal sales and marketing practices. The government has obtained multi-million and multi-billion dollar settlements under the FCA in addition to individual criminal convictions under applicable criminal statutes. In addition, certain companies that were found to be in violation of the FCA have been forced to implement extensive corrective action plans and have often become subject to consent decrees or corporate integrity agreements, restricting the manner in which they conduct their business.

The HIPAA created additional federal criminal statutes that prohibit, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors; 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; and willfully obstructing a criminal investigation of a healthcare offense. Like the AKS, the ACA amended the intent standard for certain healthcare fraud statutes under HIPAA such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

Given the significant size of actual and potential settlements, it is expected that the government will continue to devote substantial resources to investigating healthcare providers' and manufacturers' compliance with applicable fraud and abuse laws. In addition, many states have similar fraud and abuse statutes or regulations that may be broader in scope and may apply regardless of payor, in addition to items and services reimbursed under Medicaid and other state programs. Additionally, to the extent that our product candidates, once commercialized, are sold in a foreign country, we may be subject to similar foreign laws.

In addition, there has been a recent trend of increased federal and state regulation of payments made to physicians and certain other healthcare providers and teaching hospitals. The ACA, among other things, under the federal Physician Payment Sunshine Act, imposed reporting requirements on certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, for payments or other transfers of value made by them to certain covered recipients, including physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Effective January 1, 2022, these reporting obligations with respect to covered recipients have been extended to include payments and transfers of value made

to non-physician providers such as physician assistants and nurse practitioners. Covered manufacturers are required to collect and report detailed payment data and submit legal attestation to the accuracy of such data to the government each year. Failure to submit required information may result in civil monetary penalties for all payments, transfers of value or ownership or investment interests that are not timely, accurately, and completely reported in an annual submission. Additionally, entities that do not comply with mandatory reporting requirements may be subject to a corporate integrity agreement. Certain states also mandate implementation of commercial compliance programs, impose restrictions on covered manufacturers' marketing practices and/or require the tracking and reporting of gifts, compensation and other remuneration to physicians and other healthcare professionals.

We may also be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. HIPAA, as amended by HITECH and their respective implementing regulations, impose specified requirements on certain health care providers, plans, and clearinghouses, or collectively, covered entities, and their business associates, relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's security standards directly applicable to business associates, which includes independent contractors or agents of covered entities that create, receive, maintain, or transmit protected health information in connection with providing a service for or on behalf of a covered entity. HITECH also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce HIPAA and seek attorney's fees and costs associated with pursuing federal civil actions. In addition, certain states have their own laws that govern the privacy and security of health information in certain circumstances, many of which differ from each other and/or HIPAA in significant ways and may not have the same effect, thus complicating compliance efforts.

If our operations are found to be in violation of any of such laws or any other governmental regulations that apply to us, we may be subject to penalties, including, without limitation, civil and criminal penalties, damages, fines, disgorgement, the curtailment or restructuring of our operations, exclusion from participation in federal and state healthcare programs, imprisonment, contractual damages, reputational harm, and diminished profits and future earnings, any of which could adversely affect our ability to operate our business and our financial results. If any of the physicians or other providers, independent contractors, or entities with whom we do business are found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs and imprisonment, which could affect our ability to operate our business. Further, defending against any such actions can be costly, time-consuming and may require significant personnel resources. Therefore, even if we are successful in defending ourselves against any such actions that may be brought against us, our business may be impaired.

In addition to the foregoing health care laws, we are also subject to the FCPA and similar worldwide anti-bribery laws, which generally prohibit companies and their intermediaries from making improper payments to government officials or private-sector recipients for the purpose of obtaining or retaining business. The anti-corruption policy mandates compliance with the FCPA and similar anti-bribery laws applicable to our business throughout the world. However, we cannot assure you that such a policy or procedures implemented to enforce such a policy will protect us from intentional, reckless, or negligent acts committed by our employees, distributors, partners, collaborators or agents. Violations of these laws, or allegations of such violations, could result in fines, penalties or prosecution and have a negative impact on our business, results of operations and reputation.

Coverage and Reimbursement

Sales of pharmaceutical products depend significantly on the extent to which coverage and adequate reimbursement are provided by third-party payors. Third-party payors include state and federal government health care programs, managed care providers, private health insurers and other organizations. Although we currently believe that third-party payors will provide coverage and reimbursement for our product candidates, if approved, we cannot be certain of this. Third-party payors are increasingly challenging the price, examining the cost-effectiveness, and reducing reimbursement for medical products and services. In the U.S., no uniform policy of coverage and reimbursement for drugs or biological products exists, and one payor's determination to provide coverage and adequate reimbursement for a product does not assure that other payors will make a similar determination. In the U.S., the principal decisions about reimbursement for new medicines are typically made by the CMS, an agency within the HHS, as the CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare. Private third-party payors tend to follow Medicare coverage and reimbursement limitations to a substantial degree but also have their own methods and approval processes apart from Medicare determinations. Significant uncertainty exists as to the reimbursement status of newly approved healthcare products.

The U.S. government, state legislatures and foreign governments have continued implementing cost containment programs, including price controls, restrictions on coverage and reimbursement and requirements for substitution of generic 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 revenues and results. We may need to conduct expensive clinical trials to demonstrate the comparative cost-effectiveness of our product candidates. The product candidates that we develop may not be considered cost-effective and thus may not be covered or sufficiently reimbursed. It is time consuming and expensive for us to seek coverage and reimbursement from third-party payors, as each payor will make its own determination as to whether to cover a product and at what level of reimbursement. Thus, one payor's decision to provide coverage and adequate reimbursement for a product does not ensure that another payor will provide coverage or that the reimbursement levels will be adequate. Moreover, a payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Reimbursement may not be available or sufficient to allow us to sell our product candidates on a competitive and profitable basis.

Healthcare Reform

The U.S. and some foreign jurisdictions are considering or have enacted a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our product candidates profitably. Among policy makers and payors in the U.S. 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. In the U.S., the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

By way of example, in March 2010, the ACA was signed into law, intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. Among the provisions of the ACA of importance to our potential product candidates are:

- an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13.0% of the average manufacturer price for branded and generic drugs, respectively;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 70% (increased pursuant to the Bipartisan Budget Act of 2018, effective as of 2019) point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for a manufacturer's outpatient drugs to be covered under Medicare Part D;
- extension of a manufacturer's Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. These changes include, among others, the Budget Control Act of 2011, which mandates aggregate reductions to Medicare payments to providers of up to 2% per fiscal year effective April 1, 2013, and, due to subsequent legislative amendments, will remain in effect through 2032. In January 2013, President Obama signed into law the ATRA, which, among other things, further reduced Medicare payments to several providers, including hospitals and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on customers for our product candidates, if approved, and, accordingly, our financial operations.

Under the American Rescue Plan Act of 2021, the statutory cap on Medicaid Drug Rebate Program rebates that manufacturers pay to state Medicaid programs was eliminated. Elimination of this cap may require pharmaceutical manufacturers to pay more in rebates than they receive on the sale of products, which could have a material impact on our business. Further, in July 2021, an executive order, "Promoting Competition in the American Economy," was released with multiple provisions aimed at increasing competition for prescription drugs. In August 2022, Congress passed the IRA, which includes prescription drug provisions that have significant implications for the pharmaceutical industry and Medicare beneficiaries, including allowing the federal government to negotiate a maximum fair price for certain high-priced single source Medicare drugs, imposing penalties and excise tax for manufacturers that fail to comply with the drug price negotiation requirements, requiring inflation rebates for all Medicare Part B and Part D drugs, with limited exceptions, if their drug prices increase faster than inflation, and redesigning Medicare Part D to reduce out-of-pocket prescription drug costs for beneficiaries, among other changes. Various industry stakeholders have initiated lawsuits against the U.S. government asserting that the price negotiation provisions of the IRA are unconstitutional. The impact of these judicial challenges, legislative, executive, and administrative actions and any future healthcare measures and agency rules on us and the pharmaceutical industry as a whole is unclear. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our product candidates if approved. Complying with any new legislation and regulatory changes could be time-intensive and expensive, resulting in a material adverse effect on our business.

Since the enactment of the ACA, there have been judicial and Congressional challenges to certain aspects of the ACA. In June 2021, the United States Supreme Court held that Texas and other challengers had no legal standing to challenge the ACA, dismissing the case without specifically ruling on the constitutionality of the ACA. Accordingly, the ACA remains in effect in its current form. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how additional challenges and healthcare reform measures will impact the ACA. Complying with any new legislation or changes in healthcare regulation could be time-intensive and expensive, resulting in material adverse effect on our business.

At the state level, individual states are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including discounts, restrictions on certain product access and marketing cost disclosure and transparency measures. For example, a number of states are considering or have recently enacted state drug price transparency and reporting laws that could substantially increase our compliance burdens and expose us to greater liability under such state laws once we begin commercialization after obtaining regulatory approval for any of our products. For example, the FDA has authorized the state of Florida to develop a program to import certain prescription drugs from Canada for a limited period to help reduce drug costs, provided that Florida's Agency for Health Care Administration meets the requirements set forth by the FDA. Other states may follow Florida. These measures could reduce the demand for our products, if approved, or impose additional pricing pressures on how much we can charge for our products if approved.

We expect that the ACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and lower reimbursement and additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government-funded programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our product candidates. Furthermore, the current presidential administration and Congress may continue to attempt broad sweeping changes to the current health care laws. We face uncertainties that might result from modifications or repeal of any of the provisions of the ACA, including as a result of current and future executive orders and legislative actions. The impact of those changes on us and potential effect on the pharmaceutical and biotechnology industries as a whole is currently unknown. However, any changes to the ACA are likely to have an impact on our results of operations and may have a material adverse effect on our results of operations. We cannot predict what other healthcare programs and regulations will ultimately be implemented at the federal or state level or the effect any future legislation or regulation in the U.S. may have on our business.

Foreign Regulation

In addition to regulations in the U.S., we will be subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of our product candidates to the extent we choose to develop or sell any product candidates outside of the U.S. The approval process varies from country to country and the time may be longer or shorter than that required to obtain FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country.

Human Capital

Our Human Resources talent strategy relies on attracting, retaining and developing top talent that align with our culture and mission to "Outsmart Your Disease." We promote a culture that is focused on delivering treatments utilizing natural immunities, and we seek to harness our science first focus to deliver solutions to patients and families. As of December 31, 2024, we had 680 employees located across the U.S. and Italy. Among our employees, 41% are focused on research and development, 26% on manufacturing and quality, and 33% on selling, general and administrative functions. We have not been subject to labor action or union activities, and our management considers its relationship with employees to be good.

We believe that fostering a workplace that celebrates differences and strengths creates an environment that supports the inclusion and value of diverse thoughts, backgrounds and perspectives. A well-rounded culture allows for ongoing dialogue and discussions that challenge the status quo and create a learning environment that supports diversity, equity and inclusion. As part of our commitment, we continue to encourage a culture where employees can freely ask questions and raise concerns. Our annual performance review process helps support our commitment to develop and retain top talent by providing an opportunity to have open dialogue, establish goals, discuss milestones and continue to engage in opportunities to develop and cultivate the talent. Additionally, we conduct an annual employee engagement survey, and our management team makes themselves available to all employees, including 1:1s, Department Meetings and Town Hall events.

Our ongoing success will continue to depend on our ability to attract, engage and retain top talent in an ever growing competitive market. We offer a competitive compensation package to help meet the needs of our employees, incentivize performance and enhance retention. In addition to salaries, these programs include the potential to receive annual bonuses and equity awards, and a 401(k) plan, healthcare and insurance benefits, flexible spending accounts, paid time off, family leave, flexible work schedules, and an employee assistance program, among others. We work to ensure pay equity by assessing our compensation practices and working with external benchmarks and compensation consultants to design and benchmark our programs.

Organization and Development of ImmunityBio, Inc.

ImmunityBio, Inc. is incorporated in Delaware and its principal executive offices are located in San Diego, California. The company operates in one business and one reportable segment. ImmunityBio, Inc. was established following a series of mergers and name changes. For more information regarding ImmunityBio's development, see Part I, Item 1. *"Business—Organization and Development of ImmunityBio, Inc."* of our Annual Report filed with the SEC on March 19, 2024.

Available Information

Financial and other information about our company is available on our website at https://www.immunitybio.com. We make available on our website, free of charge, copies of our Annual Report, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and all amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act as soon as reasonably practicable after such reports are electronically filed with, or furnished to, the SEC. All reports we file with the SEC are available free of charge via EDGAR through the SEC website at https://www.sec.gov. We have included the web addresses of ImmunityBio and the SEC as inactive textual references only. Except as specifically incorporated by reference into this Annual Report, information on these websites, including the higher resolution images referred to in the "Founder's Vision" section of this Annual Report, is not part of this filing.

ITEM 1A. RISK FACTORS.

Investing in our securities involves a high degree of risk. You should carefully consider the risks described below, any of which may be relevant to decisions regarding an investment in or ownership of our stock. The occurrence of any of these risks could have a significant adverse effect on our reputation, business, financial condition, results of operations, growth, and ability to accomplish our strategic objectives. We have organized the description of these risks into groupings in an effort to enhance readability, but many of the risks interrelate or could be grouped or ordered in other ways, so no special significance should be attributed to the groupings or order below.

Risk Factor Summary

Risks Related to Our Financial Condition and Capital Requirements

- We are a vertically-integrated commercial stage biotechnology company with a single approved product and a limited operating history as a commercial company and have many other product candidates at the clinical stage. We have a history of operating losses, and we expect to continue to incur losses and may never be profitable, which, together with our limited operating history, makes it difficult to assess our future viability.
- We anticipate needing additional financing to fund our operations, complete the commercialization of our approved product, conduct clinical trials, and develop and commercialize our other product candidates.
- The RIPA imposes Revenue Interest Payment obligations, which may adversely affect our financial position and results of operations, as well as affirmative and negative covenants, which restrict our business operations.
- Our debt and revenue interest liability could adversely affect our cash flows and limit our flexibility to raise additional capital.
- The value of our warrants outstanding and the revenue interest liability are subject to potentially material increases and decreases based on fluctuations in the price of our common stock or projected sales and the probability of specific events, which may affect our results of operations and financial position and could adversely affect our stock price.

Risks Related to the Discovery, Development and Commercialization of our Approved Product and our Other Product Candidates

- We are substantially dependent on the successful commercialization of our approved product and the success and regulatory approval of our other product candidates. If we are unable to successfully commercialize our approved product or successfully complete clinical development of, obtain regulatory approval for, or commercialize, our other product candidates, or if we experience delays in doing so, our business will be materially harmed.
- We have limited experience as a commercial company and the sales, marketing, and distribution of our approved product or any future approved products may be unsuccessful or less successful than anticipated.
- We have developed an approved product and are developing other product candidates in combination with other therapies, which expose us to additional risks.

Risks Related to Reliance on Third Parties

- We have relied and will continue to rely on third parties and related parties to conduct some of our preclinical studies and clinical trials, manufacture products, and perform many essential services for any products that we commercialize. Any failure by a third party or related party to perform as expected, to comply with legal and regulatory requirements, to manufacture products in compliance with cGMP, or to conduct the clinical trials according to GCP guidelines, and in a timely manner, may delay or prevent our ability to commercialize our approved product, to seek or obtain regulatory approval for or commercialize our other product candidates or may subject us to regulatory sanctions.
- If third-party manufacturers, wholesalers and distributors fail to perform as expected, or fail to devote sufficient time and resources to our approved product or other product candidates, our clinical development may be delayed, our costs may be higher than expected or our other product candidates may fail to be approved, or we may fail to successfully commercialize our approved product or any other product candidates if approved.

- We use the Clinic, a related party, in some of our clinical trials which may expose us to significant regulatory risks. If our data for this site is not sufficiently robust or if there are any data integrity issues, we may be required to repeat such studies or contract with other clinical trial sites, which could delay and/or increase the cost of our development plans.
- We have formed, and may in the future form or seek, strategic alliances or enter into collaborations with third parties or additional licensing arrangements, and we may not realize the benefits of such alliances or licensing arrangements, and we may engage in disputes with such third parties, which can be costly and time consuming.

Risks Related to Healthcare and Other Government Regulations

- While we have one FDA-approved product, we may be unable to obtain additional U.S. or foreign regulatory approval and, as a result, may be unable to commercialize our other product candidates. We are and will continue to be subject to ongoing extensive regulation, regulatory obligations and continued regulatory review, which may result in significant additional expense.
- Obtaining and maintaining regulatory approval of our approved product or other product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval in other jurisdictions.
- Even though we have a regulatory approved product, we will continue to be subject to ongoing regulatory requirements concerning it and our other product candidates which may result in significant additional expenses. Additionally, our other product candidates, if approved, could be subject to labeling and other restrictions, and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our approved product or product candidates.
- If we are unable to establish adequate sales, marketing and distribution capabilities, we may not be successful in commercializing our approved product or other product candidates if and when they are approved.
- Problems related to large-scale commercial manufacturing could cause delays in product launches, an increase in product costs, product recalls or product shortages.

Risks Related to Intellectual Property

- If we are unable to obtain, maintain, protect and enforce patent protection and other proprietary rights for our approved product and our other product candidates and technologies, we may not be able to compete effectively or operate profitably and our ability to prevent our competitors from commercializing similar or identical technology and we would be adversely affected.
- If any of our owned or in-licensed patent applications do not issue as patents in any jurisdiction, we may not be able to compete effectively.
- We or our licensors, collaborators, 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 intellectual property or the patents or other intellectual property of our licensors, all of which could be expensive, time-consuming and unsuccessful, may delay or prevent the development and commercialization of our approved product and other product candidates, or may put our patents and other proprietary rights at risk.

Risks Related to Our Common Stock

- Dr. Soon-Shiong, our Founder, Executive Chairman, Global Chief Scientific and Medical Officer and principal stockholder, has significant interests in other companies which may conflict with our interests.
- Dr. Soon-Shiong, through his voting control of the company, has the ability to control actions that require stockholder approval.
- Conversion of related-party promissory notes, exercise of outstanding warrants and options to purchase our common stock, the achievement of the milestone under our outstanding CVRs, and potential additional equity issuances may dilute the ownership interest of existing stockholders or may otherwise depress the price of our common stock.
- The market price of our common stock has been and may continue to be volatile, and investors may have difficulty selling their shares.

Risks Related to Our Financial Condition and Capital Requirements

We are a vertically-integrated commercial stage biotechnology company with a single approved product and a limited operating history as a commercial company and have many other product candidates at the clinical stage. We have a history of operating losses, and we expect to continue to incur losses and may never be profitable, which, together with our limited operating history, makes it difficult to assess our future viability.

We are a vertically-integrated commercial stage biotechnology company with a limited operating history as a commercial company upon which you can evaluate our business and prospects regarding the commercialization of our approved product, and we have a broad portfolio of product candidates at various stages of development. Prior to the approval of ANKTIVA for commercial sale, we primarily generated revenues from non-exclusive license agreements related to our cell lines, the sale of our bioreactors and related consumables, and grant programs. The company expects to continue to generate revenue from these programs.

On April 22, 2024, the FDA approved ANKTIVA with BCG for the treatment of adult patients with BCG-unresponsive NMIBC with CIS with or without papillary tumors for commercial sale, and we have commenced generating revenue, although we expect it to take some time to generate significant revenue from our approved product. We can provide no assurance when, or if, this will occur. We do not expect additional revenue from our other product candidates unless and until we obtain regulatory approval of and commercialize any of such other product candidates, and we do not know when, or if, this will occur. In addition, we have limited experience and have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the biotechnology industry, including in connection with obtaining marketing approvals, manufacturing a commercial-scale product or arranging for a third party to do so on our behalf, and conducting sales and marketing activities necessary for successful product commercialization. Because of the numerous risks and uncertainties associated with the commercialization of our approved product and other development efforts, we are unable to predict when we may become profitable, if at all.

Since the commencement of our operations, we have incurred significant losses each year, and, as of December 31, 2024, we had an accumulated deficit of $3.4 billion. We expect to continue to incur significant expenses as we seek to expand our business, including in connection with conducting research and development across multiple therapeutic areas, participating in clinical trial activities, continuing to acquire or in-license technologies, maintaining, protecting and expanding our intellectual property, seeking regulatory approvals, increasing our manufacturing capabilities and, upon successful receipt of FDA approval, commercializing our other product candidates. Furthermore, the timing and magnitude of sales of our approved product and other revenues remain uncertain and may take a significant amount of time to materialize.

We expect our expenses and net losses to increase significantly as we continue to commercialize our approved product, continue to develop and seek regulatory approvals for our other product candidates, and plan to commercialize other approved products, if any, as well as hire additional personnel, protect our intellectual property and incur additional costs associated with operating as a public company. Since ANKTIVA is approved for use with BCG (and currently TICE BCG is the only FDA-approved strain of BCG available in the U.S., except for rBCG available in limited quantities through our agreement with Serum Institute pursuant to an EAP), any shortage or supply chain issues associated with TICE BCG could impact the demand for ANKTIVA and our ability to commercialize our approved product.

Our net losses may fluctuate significantly from quarter to quarter and year to year, depending on sales, the timing of our clinical studies and trials, associated manufacturing needs, commercialization activities of our approved product, and any of our other product candidates, if they are approved, and our expenditures on other research and development activities.

We also face the risks associated with the shift from development to commercialization of new products based on innovative technologies. Our ability to achieve profitability, if ever, is dependent upon, among other things, obtaining regulatory approvals for additional product candidates and successfully commercializing our approved product, and other product candidates alone or with third parties. However, our operations may not become profitable even with commercial sales of our approved product or other product candidates, even if they are successfully developed, approved and thereafter commercialized. Even if we do become profitable, we may not be able to sustain or increase our profitability on a quarterly or annual basis. As a result, it may be more difficult for you to assess our future viability than it could have been if we had a longer operating history.

We anticipate needing additional financing to fund our operations, complete the commercialization of our approved product, conduct clinical trials, and develop and commercialize our other product candidates. If we are unable to obtain such financing when needed or on acceptable terms, we may be unable to successfully commercialize our approved product or develop and commercialize our other product candidates. If we are unable to obtain such financing when needed or on acceptable terms, we could be forced to delay, limit, reduce, or terminate our development programs, commercialization efforts, and/or other operations.

The development of biopharmaceutical products, including conducting preclinical studies and clinical trials, is a very time-consuming, expensive and uncertain process that takes years to complete. Our operations have consumed substantial amounts of cash since inception. A significant portion of our funding has been in the form of related-party promissory notes. As of December 31, 2024, our indebtedness was comprised of a $505.0 million convertible promissory note held by an entity affiliated with Dr. Soon-Shiong.

As of December 31, 2024, we held cash and cash equivalents, and marketable securities totaling $149.8 million. We will need to obtain additional financing to fund our future operations, including the commercialization of our approved product and the development and commercialization of our other product candidates. Changing circumstances may cause us to increase our spending significantly faster than we currently anticipate and we may need to raise additional funds sooner than we presently anticipate. Moreover, research and development and our operating costs and fixed expenses such as rent and other contractual commitments, including those for our research collaborations, are substantial and are expected to increase in the future.

Unless and until we can generate a sufficient amount of revenue, we may finance future cash needs through public or private equity offerings, license agreements, debt financings, collaborations, strategic alliances or marketing and/or distribution arrangements. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms, or at all.

To the extent that we raise additional capital through the sale of equity or equity-linked securities (including warrants), convertible debt, our shelf registration statements, or other offerings, or if any of our current debt is converted into equity or if our existing warrants are exercised, your ownership interest will be diluted, and the liquidation or other preferences may adversely affect your rights as a stockholder. If we incur additional indebtedness, our fixed payment obligations will increase, and we may have to comply with certain restrictive covenants that are similar to those associated with the revenue interest liability, such as limitations on our ability to incur additional debt, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. If we raise additional funds through strategic partnerships and alliances and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or product candidates, or grant licenses on terms unfavorable to us, or exercise our Call Option (as defined in the RIPA) to purchase the outstanding revenue interest liability, which will require us to generate a significant amount of cash flow to offset these outflows. We have no committed source of additional capital, and if we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may be required to delay or reduce the scope of or eliminate one or more of our research or development programs or our commercialization efforts. See *"—Our payment obligations under the RIPA may adversely affect our financial position and results of operations and our ability to raise additional capital, which in turn may increase our vulnerability to adverse regulatory developments or economic or business downturns"* and Note 11 *"Revenue Interest Purchase Agreement"* of the "Notes to Consolidated Financial Statements" that appears in Part II, Item 8. "Financial Statements and Supplementary Data" of this Annual Report for more information. Our current license and collaboration agreements may also be terminated if we are unable to meet the payment obligations under those agreements. As a result, we may seek to access the public or private capital markets whenever conditions are favorable, even if we do not have an immediate need for additional capital at that time.

Our payment obligations under the RIPA may adversely affect our financial position and results of operations and our ability to raise additional capital, which in turn may increase our vulnerability to adverse regulatory developments or economic or business downturns.

On December 29, 2023, we entered into the RIPA with Infinity and Oberland. Pursuant to the RIPA, Oberland acquired certain Revenue Interests from us for a gross purchase price of $200.0 million paid on closing, less certain transaction expenses. In addition, on May 13, 2024, Oberland purchased additional Revenue Interests from us in exchange for a $100.0 million Second Payment, which we requested upon satisfaction of certain conditions specified in the RIPA, including the receipt of approval from the FDA of our BLA for ANKTIVA with BCG for the treatment of adult patients with BCG-unresponsive NMIBC with CIS with or without papillary tumors on or before June 30, 2024. In consideration for the aforementioned payments, Oberland has the right

to receive quarterly Revenue Interest Payments from us based on, among other things, our worldwide net sales, excluding those in China, which are tiered payments ranging from 4.50% to 10.00%, subject to increase or decrease, following December 31, 2029 depending on whether the aggregate payments made to Oberland as of that date met or exceeded the Cumulative Purchaser Payments (as defined in the RIPA). In addition, if the aggregate payments to Oberland as of December 31, 2029 do not equal or exceed the amount of the Cumulative Purchaser Payments, then we are obligated to make a one-time payment to Oberland in an amount equal to 100% of the Cumulative Purchaser Payments, less the aggregate amount of our previous payments to Oberland as of December 31, 2029 (the True-Up Payment, as defined in the RIPA). See Note 11 *"Revenue Interest Purchase Agreement"* of the "Notes to Consolidated Financial Statements" that appears in Part II, Item 8. "Financial Statements and Supplementary Data" of this Annual Report for more information.

The RIPA and our payment obligations to Oberland could have important negative consequences to holders of our securities. For example, a portion of our cash flow from operations will be needed to make required payments to Oberland and will not be available to fund future operations.

Payment requirements under the RIPA will increase our cash outflows. Our future operating performance is subject to market conditions and business factors that are beyond our control. If our cash inflows and capital resources are insufficient to allow us to make required payments, we may have to reduce or delay capital expenditures, sell assets or seek additional capital. If we raise funds by selling additional equity, such sales will result in dilution to our stockholders. There is no assurance that if we are required to secure funding, we can do so on terms acceptable to us, or at all. Failure to pay amounts owed to Oberland when due would result in a default under the RIPA and could result in foreclosure on all or substantially all of our assets, which would have a material adverse effect.

The RIPA contains affirmative and negative operational covenants and events of default, which may prevent us from capitalizing on business opportunities and taking some corporate actions and give rise to a Put Option in favor of Oberland, which could have a material adverse effect on our financial condition and business operations.

The RIPA contains affirmative and negative covenants and events of default, including covenants and restrictions that, among other things, restrict our ability to incur liens, incur additional indebtedness, make loans and investments, enter into transactions with affiliates, engage in mergers and acquisitions, engage in asset sales and exclusive licensing arrangements, and declare dividends to our stockholders, in each case, subject to certain exceptions set forth in the RIPA. Additionally, Oberland has a Put Option enabling them to terminate the RIPA and to require the company to repurchase the Revenue Interests upon enumerated events such as a bankruptcy event, failure to make a payment, an uncured material breach, default on certain third-party agreements, a breach or default under any subordination agreements with respect to indebtedness to existing stockholders, any right to repurchase or accelerate debt instruments like permitted convertible notes, existing stockholder indebtedness, or subordinated notes during certain time periods, judgments in excess of certain amounts against us, a material adverse effect, the loss of regulatory approval of our approved product, or a change of control. The triggering of the Put Option, including by our failure to comply with these covenants, would permit Oberland to declare certain amounts to be immediately due and payable. If we were to default under the terms of the RIPA, including by failure to make such accelerated payments, Oberland could exercise remedies, including initiating foreclosure proceedings against all or substantially all of our assets. Oberland's right to repayment is senior to the rights of the holders of our common stock. Any triggering of the Put Option or other declaration by Oberland of an event of default under the RIPA could significantly harm our financial condition, business and prospects and could cause the price of our common stock to decline.

Our debt and revenue interest liability could adversely affect our cash flows and limit our flexibility to raise additional capital.

We have a significant amount of debt and a revenue interest liability and may need to incur additional debt to support our growth. As of December 31, 2024, our indebtedness was comprised of a $505.0 million convertible promissory note held by an entity affiliated with Dr. Soon-Shiong and a revenue interest liability with Oberland in excess of $300.0 million. The total amount paid to Oberland depends on when we repay this debt. See Note 11 *"Revenue Interest Purchase Agreement"* of the "Notes to Consolidated Financial Statements" that appears in Part II, Item 8. "Financial Statements and Supplementary Data" of this Annual Report for more information about the revenue interest liability.

Our substantial amount of debt could have important consequences and could:

- require us to dedicate a substantial portion of our cash and cash equivalents to make interest and principal payments on our debt and revenue interest liability payments, reducing the availability of our cash and cash equivalents and cash flow from operations to fund future capital expenditures, working capital, execution of our strategy and other general corporate requirements;
- increase our cost of borrowing and even limit our ability to access additional debt to fund future growth;
- increase our vulnerability to general adverse economic and industry conditions and adverse changes in governmental regulations;
- limit our flexibility in planning for, or reacting to, changes in our business and industry, which may place us at a disadvantage compared with our competitors; and
- limit our ability to borrow additional funds, even when necessary to maintain adequate liquidity, which would also limit our ability to further expand our business.

The occurrence of any of the foregoing factors could have a material adverse effect on our business, results of operations and financial condition.

Further, the company's ability to make scheduled payments of the principal of, potential Test Date payments of, to pay interest or royalties on, or to refinance any current or future indebtedness, including the related-party promissory note or the revenue interest liability, depends on our future performance, which is subject to economic, financial, competitive and other factors beyond our control. Our business may not generate sufficient cash flows from operations in the future to service our indebtedness, pay the revenue interest liability, and make necessary capital expenditures. If we are unable to generate such cash flows, we may be required to adopt one or more alternatives, such as selling assets, restructuring indebtedness, including the revenue interest liability, or obtaining additional equity or equity-linked capital on terms that may be onerous or highly dilutive. Our ability to refinance our indebtedness, including the revenue interest liability, at maturity or otherwise, will depend on the capital markets and our financial condition at such time. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations.

There can be no assurance that we can refinance the related-party promissory note or revenue interest liability or what terms will be available in the market at the time of refinancing. Furthermore, if prevailing interest rates or other factors at the time of refinancing result in higher interest rates upon refinancing, then the interest expense relating to the refinancing would increase. These risks could materially adversely affect our financial condition, cash flows and results of operations.

The value of our warrants outstanding and the revenue interest liability are subject to potentially material increases and decreases based on fluctuations in the price of our common stock or projected sales and the probability of specific events, which may affect our results of operations and financial position and could adversely affect our stock price.

In connection with our RDO during the year ended December 31, 2023, we entered into warrant agreements with certain institutional investors that allow such investors to purchase up to an aggregate total of 28,641,911 shares of our common stock at an exercise price of $3.2946 per share. As of December 31, 2024, 6,399,171 warrants were exercisable with an expiration date of July 24, 2026.

We account for the warrants as derivative instruments, and changes in the fair value of the warrants are included in *other income (expense), net*, on the consolidated statement of operations for each reporting period. As of December 31, 2024, the fair value of warrant liabilities included in the consolidated balance sheet was $8.6 million. We use the Black-Scholes option pricing model to determine the fair value of the warrants. As a result, the valuation of these derivative instruments is subjective, and the Black-Scholes option pricing model requires the input of subjective assumptions, including the expected stock price volatility and probability of a fundamental transaction (a strategic merger or sale). Changes in these assumptions can materially affect the fair value estimate. We could, at any point in time, ultimately incur amounts different than the carrying value, which could have a significant impact on our results of operations and financial position.

We account for the revenue interest liability as a liability, net of a debt discount comprised of deferred issuance costs, the fair value of a freestanding option agreement related to the SPOA, and the fair value of embedded derivatives requiring bifurcation on the consolidated balance sheet. The company imputes interest expense associated with this liability using the effective interest rate method. The effective interest rate is calculated based on the rate that would enable the debt to be repaid in full over the anticipated life of the arrangement. Interest expense is recognized over the estimated term on the consolidated statement of operations. The interest rate on the liability and the underlying value of the bifurcated embedded derivative may vary during the term of the agreement depending on a number of factors, including the level of actual and forecasted net sales, and in the case of the derivative, specific probabilities associated with RIPA Put/Call events or Test Date payments underlying our Monte Carlo analysis. The company evaluates the interest rate quarterly based on actual and forecasted net sales utilizing the prospective method. A significant increase or decrease in actual or forecasted net sales will materially impact the revenue interest liability and/or the bifurcated embedded derivative, interest expense, and the time period for repayment.

Fluctuations in warrant, revenue interest liability, and derivative values, and changes in the assumptions and factors used in the model may impact our operating results, making it difficult to forecast our operating results and making period-to-period comparisons less predictive of future performance. In one or more future quarters, our results of operations may fall below the expectations of securities analysts and investors. In that event, the market price of our common stock could decline. In addition, the market price of our common stock may fluctuate or decline regardless of our operating performance.

The accounting method for convertible debt securities could have a material effect on our reported financial results.

We entered into a second amended and restated promissory note with Nant Capital on December 10, 2024 in connection with an equity offering. Pursuant to the terms of the second amended and restated promissory note, Tranche 1 of the prior promissory note (the December 2023 Promissory Note) with a principal amount of $125.0 million and Tranche 2 of the December 2023 Promissory Note with a principal amount of $380.0 million were combined into one convertible promissory note with a principal amount of $505.0 million (the December 2024 Promissory Note).

The December 2024 Promissory Note was accounted for as part of a debt extinguishment, in accordance with FASB ASC Topic 470-50, *Debt – Modifications and Extinguishments* (ASC 470-50), as the amendment was substantially different than the terms of the promissory notes prior to the amendment. The company elected the fair value option of accounting under FASB ASC Topic 825, *Financial Instruments* (ASC 825), for the December 2024 Promissory Note. As a result of the fair value option election, the December 2024 Promissory Note and the embedded derivative were accounted for as a single instrument in accordance with FASB ASC Topic 815, *Derivatives and Hedging* (ASC 815). Changes in fair value of the December 2024 Promissory Note are recorded as a component of *other income (expense, net,* on the consolidated statement of operations. There is no current observable market for the December 2024 Promissory Note and, as such, we determined the fair value by using the binomial lattice model with significant unobservable inputs including an expected market yield, an expected volatility, and a risk-free rate. The changes in fair value of the December 2024 Promissory Note may have a substantial effect and may have a negative impact on our statement of financial position and statement of operations. It is difficult to predict the effect on our future financial results as the significant inputs are outside of our control.

We invest our cash on hand in various financial instruments which are subject to risks that could adversely affect our business, results of operations, liquidity and financial condition.

We have typically invested our cash in a variety of financial instruments, including investment-grade short- to intermediate-term corporate debt securities, government-sponsored securities and European bonds; however, after our entry into the RIPA, we can no longer invest our excess funds in corporate or European bonds. Certain of our investments are subject to credit, liquidity, market, and interest rate risk. Such risks, including the failure or severe financial distress of the financial institutions that hold our cash and cash equivalents, and investments, may result in a loss of liquidity, impairment to our investments, realization of substantial future losses, or a complete loss of the investments in the long-term, which may have a material adverse effect on our business, results of operations, liquidity and financial condition. To manage the risk to our investments, we maintain an investment policy that, among other things, limits the amount that we may invest in any one issue or any single issuer and requires us to only invest in high credit quality securities to preserve liquidity.

Our ability to use NOLs and research and development credits to offset future taxable income may be subject to certain limitations.

In general, under Sections 382 and 383 of the Code, a corporation that undergoes an ownership change is subject to limitations on its ability to utilize its pre-change NOLs or credits, to offset future taxable income or taxes. For these purposes, an ownership change generally occurs when the aggregate stock ownership of one or more stockholders or groups of stockholders who own at least 5% of a corporation's stock increases its ownership by more than 50 percentage points over its lowest ownership percentage within a specified testing period ("ownership shift"). We have not conducted a complete study to assess whether a change of control has occurred or whether there have been multiple changes of control since inception due to the significant complexity and cost associated with such a study. If we have experienced a change of control, as defined by Section 382, at any time since inception (including as a result of the March 2021 merger which pursuant to which NantKwest and NantCell combined their businesses), utilization of the NOL carryforwards or research and development tax credit carryforwards would be subject to an annual limitation under Section 382. Any limitation may result in expiration of a portion of the NOL carryforwards or research and development tax credit carryforwards before utilization. In addition, our NOLs or credits may also be impaired under state law. Accordingly, we may not be able to utilize a material portion of our NOLs or credits.

Since we will need to raise substantial additional funding to finance our operations, we may experience further ownership shifts in the future, some of which may be outside of our control. Limits on our ability to use our pre-change NOLs or credits to offset U.S. federal taxable income could potentially result in increased future tax liability to us if we earn net taxable income in the future. In addition, under the legislation commonly referred to as the TCJA, as modified by the Coronavirus Aid, Relief, and Economic Security Act, the amount of NOLs generated in taxable periods beginning after December 31, 2017, that we are permitted to deduct in any taxable year beginning after December 31, 2020 is limited to 80% of our taxable income in such year, where taxable income is determined without regard to the NOL deduction itself. The TCJA allows post-2017 unused NOLs to be carried forward indefinitely. Similar rules apply under state tax laws. In addition, some states, e.g., California, may suspend the use of NOL carryovers that may result in state taxable income and liabilities.

Our transfer pricing policies may be subject to challenge by the IRS or other taxing authorities.

Our intercompany relationships are subject to complex transfer pricing regulations administered by taxing authorities in various jurisdictions. The relevant tax authorities may disagree with our determinations as to the value of assets sold or acquired or income and expenses attributable to specific jurisdictions. If such a disagreement were to occur, and our position were not sustained, we could be required to pay additional taxes, interest and penalties, which could result in one-time tax charges, higher effective tax rates, reduced cash flows, and lower overall profitability of our operations. We believe that our consolidated financial statements reflect adequate reserves to cover such a contingency, but there can be no assurances in that regard.

Unanticipated changes in effective tax rates or adverse outcomes resulting from new tax statutes or regulations, examination of our income or other tax returns could expose us to greater than anticipated tax liabilities.

The tax laws applicable to our business, including the laws of the U.S. and other jurisdictions, are subject to change, interpretation and certain jurisdictions may aggressively interpret their laws to raise additional tax revenue. It is possible that tax authorities may disagree with certain positions we have taken, are currently taking or will take, and any adverse outcome of such a review or audit could have a negative effect on our financial position and results of operations. Further, the determination of our provision for income taxes and other tax liabilities requires significant judgment by management, and there are transactions where the ultimate tax determination is uncertain. Although we believe that our estimates are reasonable, the ultimate tax outcome may differ from the amounts recorded on the consolidated financial statements and may materially affect our financial results in the period or periods for which such determination is made.

In addition, tax laws are dynamic and subject to change as new laws are passed and new interpretations of the law are issued or applied. For example, in August 2022, the U.S. enacted the IRA, which imposes a 15% minimum tax on the adjusted financial statement income of certain large corporations, as well as a 1% percent excise tax on corporate stock repurchases by publicly traded companies. Additionally, for taxable years beginning on or after January 1, 2022, the Code eliminated the right to deduct research and development expenditures currently and requires taxpayers to capitalize and amortize U.S. and foreign research and development expenditures over 5 and 15 tax years, respectively. These updates, as well as any other changes to tax laws that are enacted, could adversely affect our tax liability.

Risks Related to the Discovery, Development and Commercialization of our Approved Product and our Other Product Candidates

We are substantially dependent on the successful commercialization of our approved product and the success and regulatory approval of our other product candidates. If we are unable to successfully commercialize our approved product or successfully complete clinical development of, obtain regulatory approval for, or commercialize, our other product candidates, or if we experience delays in doing so, our business will be materially harmed.

Prior to the approval of ANKTIVA with BCG for the treatment of adult patients with BCG-unresponsive NMIBC with CIS with or without papillary tumors for commercial sale, we primarily generated revenues from non-exclusive license agreements related to our cell lines, the sale of our bioreactors and related consumables, and grant programs. The company expects to continue to generate revenue from these programs.

Until April 2024, we had no clinical products approved for commercial sale and thus had not generated any revenue from therapeutic and vaccine product candidates that are or were under development. In addition, now that we have received FDA approval for ANKTIVA with BCG for the treatment of adult patients with BCG-unresponsive NMIBC with CIS with or without papillary tumors, we have begun to generate revenue although we expect it to take some time to generate significant revenue from our approved product and we can provide no assurance when, or if, this will occur. We began commercial distribution of our approved product in May 2024; however, we can provide no assurance with respect to our future revenues, both in terms of amounts and pace, market acceptance, reimbursement from third-party payors, or the profitability of our approved product or any other product candidate for which we may obtain approval. We are required to comply with certain post-marketing commitments, including completion of our QUILT 3032 clinical trial and annual reporting for up to four years, with a final report submission to FDA by the end of 2029. Our business currently depends heavily on our ability to successfully commercialize our approved product in the U.S. and in other jurisdictions where we may obtain marketing approval. We may never be able to successfully commercialize our approved product or meet our, or analysts or other third parties' expectations with respect to revenues. We have never marketed, sold, or distributed for commercial use any pharmaceutical product other than our approved product, with respect to which we recently began efforts to initiate commercial sales. There is no guarantee that the infrastructure, systems, processes, policies, relationships, and materials we have built for the launch and commercialization of our approved product in the U.S. or elsewhere will be sufficient for us to achieve success at the levels we expect.

We may encounter issues and challenges in commercializing our approved product and generating substantial revenues. We may also encounter challenges related to reimbursement of our approved product, including potential limitations in the scope, breadth, availability, or amount of reimbursement covering our approved product. Similarly, healthcare settings or patients may determine that the financial burdens of treatment are not acceptable and as a result physicians may be reluctant to recommend our approved product to their patients. We may face other limitations or issues related to the price of our approved product. Our results may also be negatively impacted if we have not adequately sized our field teams, or our physician segmentation and targeting strategy is inadequate or if we encounter deficiencies or inefficiencies in our infrastructure or processes. Other factors that may hinder our ability to successfully commercialize approved product, or any of our other product candidates if or when approved and generate substantial revenues, include:

- the acceptance of our approved product by patients and the medical community, including industry groups and third-party payors;
- the ability of our third-party manufacturer(s) to manufacture commercial supplies of our approved product at acceptable costs, to remain in good standing with regulatory agencies, and to maintain commercially viable manufacturing processes that are, to the extent required, compliant with cGMP regulations;
- our ability to remain compliant with laws and regulations that apply to us and our commercial activities;
- FDA-mandated package-insert requirements and successful completion of FDA post-marketing requirements;
- the actual market size for our approved product, which may be different than expected;
- the length of time that patients who are prescribed our drug remain on treatment;
- our ability to obtain marketing approval for our approved product outside of the U.S.;
- the sufficiency of our drug supply to meet commercial and clinical demands, which could be negatively impacted if our projections regarding the potential number of patients are inaccurate, we are subject to unanticipated regulatory requirements, or our current drug supply is destroyed, or negatively impacted at our manufacturing sites, storage sites, or in transit;

- the availability of reimbursement for our approved product and physicians' understanding regarding the same;
- our ability to effectively compete with other therapies that may emerge for the treatment of bladder cancer; and
- our ability to maintain, enforce, and defend third party challenges to our intellectual property rights in and to our approved product or any of our other product candidates.

Any of these issues could impair our ability to successfully commercialize our approved product or to generate substantial revenues or profits or to meet our expectations with respect to the amount or timing of revenues or profits. Any issues or hurdles related to our commercialization efforts may materially adversely affect our business, results of operations, financial condition, and prospects. There is no guarantee that we will be successful in our launch or commercialization efforts with respect to our approved product. We may also experience significant fluctuations in sales of our approved product from period to period and, ultimately, we may never generate sufficient revenues from our approved product to reach or maintain profitability or sustain our anticipated levels of operations. Any inability on our part to successfully commercialize our approved product in the U.S., and any other international markets where it may subsequently be approved, or any significant delay, could have a material adverse impact on our ability to execute upon our business strategy.

In addition, while we are pursuing and anticipating certain additional regulatory submissions in 2025 following discussions with the FDA, such as a potential supplemental BLA submission for BCG-unresponsive NMIBC patients in the papillary indication, a BLA for second-line and third-line treatment of patients with NSCLC who are progressing on CPIs, and a potential BLA for the indication of reversal of lymphopenia in patients receiving standard-of-care chemotherapy and/or radiation and for the treatment of locally advanced or metastatic pancreatic cancer, among others, the regulatory review process is dynamic and highly uncertain. Even if we are able to prepare and submit these regulatory submissions on the anticipated timeline, there can be no assurance that the FDA will accept the BLAs and other regulatory submissions for filing and review, and there can be no assurance that the FDA will ultimately approve such BLAs and submissions if accepted for filing and review.

Further, we have invested a significant portion of our efforts and financial resources in the development of ANKTIVA, our novel antibody-cytokine fusion protein, and our other product candidates, second-generation hAd5 vaccine candidates, and our NK cell therapy candidates. Our other product candidates will require additional clinical and non-clinical development, regulatory approval, commercial manufacturing arrangements, enhancement of our commercial organization and service providers, significant marketing efforts, and further investment before we can generate any revenue from the sale of these other potential products. We expect to invest heavily in our other current product candidates and in any future product candidates that we may develop. Our product candidates are susceptible to the risks of failure inherent at any stage of product development, including the appearance of unexpected adverse events or failure to achieve primary endpoints in clinical trials. Furthermore, we cannot assure you that we will meet our timelines for current or future clinical trials, including post-market study requirements for our approved product, which may be delayed or not completed for a number of reasons. Additionally, our ability to generate revenues from our approved product and any other combination therapy products will depend on the availability of the other therapies used in combination therewith, including BCG, with which our approved product and other product candidates are intended to be used. In particular, there has been a shortage of TICE BCG in the U.S. According to the American Urological Association, Merck is the sole manufacturer and supplier of TICE BCG in the U.S. and many other countries around the world. Increasing demand for BCG has led to supply constraints for TICE BCG, which could materially impact the demand for our approved product and our ability to commercialize our approved product, and our efforts to introduce an alternative source of BCG in connection with our collaboration with the Serum Institute may not be successful.

We have limited experience as a commercial company and the sales, marketing, and distribution of our approved product or any future approved products may be unsuccessful or less successful than anticipated.

We recently began commercializing our approved product in the U.S. As a company, we have no prior experience commercializing a product. The success of our commercialization efforts for our approved product and any future approved products is difficult to predict and subject to the effective execution of our business plan, including, among other things, the continued development of our internal and external sales, marketing, and distribution capabilities and our ability to navigate the significant expenses and risks involved with the development and management of such capabilities.

For example, we have hired and contracted for service providers in areas to support commercialization, including in sales management, sales representatives, marketing, access and reimbursement, sales support, and distribution. There are significant expenses and risks involved with establishing our sales, marketing, and distribution capabilities, including our ability to hire or contract, retain, and appropriately incentivize qualified individuals, provide adequate training to sales and marketing personnel, and effectively manage geographically dispersed sales and marketing teams to generate sufficient demand. Any failure or delay in the development of these capabilities could delay or negatively affect the success of our commercialization efforts and our business. For example, the commercialization of our approved product may not develop as planned or anticipated, which may require us to, among others, adjust or amend our business plan and incur significant expenses.

Further, given our lack of experience commercializing products, we do not have a track record of successfully executing on the commercialization of an approved product. If we are unsuccessful in accomplishing our objectives and executing on our business plan, or if the commercialization of our approved product does not develop as quickly as planned, or any future approved products does not develop as planned, we may require significant additional capital and financial resources, we may not become profitable, and we may not be able to compete against more established companies in our industry.

We have developed an approved product and are developing other product candidates in combination with other therapies, which expose us to additional risks.

We have developed an approved product and are developing other product candidates in combination with one or more other therapies. We are studying ANKTIVA therapy along with other products and product candidates, such as BCG, CPIs, hAd5 TAAs, PD-L1 t-haNK, and M-ceNK. Since we have developed a product, or if we choose to develop other products for use in combination with an approved therapy, we are subject to the risk that the FDA, EMA or comparable foreign regulatory authorities in other jurisdictions could revoke approval of, or that safety, efficacy, manufacturing or supply issues could arise with the therapy used in combination with our approved product or our other product candidates. In particular, supply chain issues or shortages of other products used in combination with our approved product or any other product candidates could impact our ability to obtain FDA regulatory approval, meet clinical trial timelines, and commercialize our approved product or other product candidates. The FDA may require us to use more complex clinical trial designs in order to evaluate the contribution of each product and product candidate to any observed effects. To the extent that we do not have rights to already approved products, this may require us to work with another company to satisfy such a requirement or increase our cost of development. It is possible that the results of these trials could show that any positive results are attributable to the already approved product. Following product approval, the FDA may require that products used in conjunction with each other be cross labeled for combined use. If the therapies we use in combination with our approved product or our other product candidates are replaced as the standard-of-care for the indications we choose for our approved product or any of our other product candidates, the FDA or comparable foreign regulatory authorities 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.

In addition, unapproved therapies face the same risks described with respect to our product candidates currently in development and clinical trials, including the potential for serious adverse effects, delays in clinical trials and lack of FDA approval. If the FDA or comparable foreign regulatory authorities do not approve or revoke their approval of these other therapies, or if safety, efficacy, quality, manufacturing or supply issues arise with, the therapies we choose to evaluate in combination with any of our product candidates, we may be unable to obtain approval of or market such other combination therapies.

Our clinical trials may fail to adequately demonstrate the safety and efficacy of our product candidates, which would prevent or delay regulatory approval and commercialization of other product candidates.

Our research and development programs of our other non-FDA-approved product candidates are at various stages of development. The clinical trials of our product candidates as well as the manufacturing and marketing of our product candidates will be subject to extensive and rigorous review and regulation by numerous government authorities in the U.S. and in other countries where we intend to test and market our product candidates. Before obtaining regulatory approvals for the commercial sale of any of our other product candidates, we must demonstrate through lengthy, complex, and expensive preclinical testing and clinical trials that our product candidates are safe, pure, and potent for use in their target indications. Each product candidate must demonstrate an adequate risk vs. benefit profile in its intended patient population and for its intended use. The risk/benefit profile required for product licensure will vary depending on these factors and may include not only the ability to show tumor shrinkage, but also adequate duration of response, a delay in the progression of the disease, and/or improvement in survival. For example, response rates from the use of our product candidates or their contribution of effect may not be sufficient to obtain regulatory

approval unless we can also show an adequate duration of response. The clinical trials for our product candidates under development may not be completed on schedule, and regulatory authorities may ultimately disagree with our chosen endpoints or may find that our studies or study results do not support product approval. The FDA or foreign regulatory authorities may not interpret the results as we do or accept the therapeutic effects as valid endpoints in clinical trials necessary for market approval, or they may find that our clinical trial design or conduct does not meet the applicable approval requirement, and more trials could be required before we submit our product candidates for approval. Success in early clinical trials does not ensure that large-scale clinical trials will be successful, nor does it predict final results. Product candidates in later stages of clinical trials may fail to show the desired safety, tolerability, and efficacy traits despite having progressed through preclinical studies and initial clinical trials and after reviewing test results, we or our collaborators may abandon projects that we might previously have believed to be promising.

In addition, we do not have data on possible harmful long-term effects of our product candidates and do not expect to have this data in the near future. As a result, our ability to generate clinical safety and effectiveness data sufficient to support submission of a marketing application or commercialization of our product candidates is uncertain and is subject to significant risk.

The ongoing shortage of TICE BCG in the U.S. may adversely impact market uptake of ANKTIVA and it may also delay our ability to execute our clinical trials or seek new approvals.

There is an ongoing shortage of TICE BCG in the U.S., which may adversely impact market uptake of our approved product. The TICE BCG shortage may impact the number of patients who are treated with BCG for NMIBC with CIS with or without papillary tumors, therefore limiting the pool of BCG-unresponsive patients who may be candidates for our approved product. In addition, the TICE BCG shortage may also constrain the number of patients we can treat with our approved product since our product is administered along with BCG. In addition, we are currently enrolling patients in our Phase 2b blinded, randomized, two-cohort, open-label, multi-center trial of intravesical BCG with ANKTIVA vs. BCG alone, in BCG-naïve patients with high-grade NMIBC with CIS (Cohort A) and NMIBC papillary (Cohort B), which is impacted by the availability of TICE BCG. If we do not complete new trials timely, our ability to generate clinical safety and effectiveness data sufficient to support submission of a marketing application or commercialization of our product candidates in new indications could harm our business, operating results, prospects or financial condition. In addition, our efforts to introduce an alternative source of BCG in connection with our collaboration with Serum Institute (including a recent EAP approved by the FDA) and ultimately obtain regulatory approval for such alternative BCG supply may not be successful in mitigating the TICE BCG shortage, or at all.

We may choose to expend our limited resources on programs that do not yield successful product candidates or additional indications and may fail to capitalize on other indications and product candidates that may ultimately have been more profitable or had a greater likelihood of success.

We do not have sufficient resources to pursue development of all or even a substantial portion of the potential opportunities that we believe will be afforded to us by our product candidates. Because we have limited resources and access to capital to fund our operations, our management must make strategic decisions as to which product candidates and indications to pursue and how much of our resources to allocate to each. Our management must also evaluate the benefits of developing in-licensed or jointly owned technologies, which in some circumstances we may be contractually obligated to pursue, relative to developing other product candidates, indications or programs. Our management has broad discretion to suspend, scale down, or discontinue any or all of these development efforts, or to initiate new programs to treat other diseases. If we select and commit resources to opportunities that we are unable to successfully develop, or we forego more promising opportunities, our business, financial condition, and results of operations will be adversely affected.

Our projections regarding the market opportunities for our approved product and our other product candidates may not be accurate, and the actual market for our approved product and other product candidates may be smaller than we estimate.

Since our approved product, current product candidates, and any future product candidates represent novel approaches to treating various conditions, it may be difficult to accurately estimate the potential revenues from our approved product and these other product candidates. Accordingly, we may spend significant capital trying to successfully commercialize our approved product or obtain approval for our other product candidates that have an uncertain commercial market. Our projections of addressable patient populations that may benefit from treatment with our approved product or other product candidates are based

on our beliefs and estimates of the therapeutic benefit and adverse event profile of our approved product and other product candidates. These estimates, which have been derived from a variety of sources, including scientific literature, preclinical and clinical studies, surveys of clinics, patient foundations, or market research by third parties, may prove to be incorrect. Further, new studies or approvals of new therapeutics may change the estimated incidence or prevalence of these diseases. The number of patients may turn out to be lower than expected. Additionally, the potentially addressable patient population for our approved product or other product candidates may be limited or may not be amenable to treatment with our approved product or other product candidates and may also be limited by the cost of our treatments and the reimbursement of those treatment costs by third-party payors. Even if we obtain significant market share for our approved product or other product candidates, because the potential target populations may be small, we may never achieve profitability without obtaining regulatory approval for additional indications.

There can be no assurance that we will complete a strategic partnership transaction on acceptable terms, or at all.

We continue to explore potential global strategic partnership transactions for commercialization of ANKTIVA for certain indications. Factors that may impact our ability, or decision, to enter into such a strategic partnership, include, without limitation, the put/call features of the RIPA that may be triggered by entry into a strategic partnership depending on its scope and terms, and ultimately there can be no assurance that we will complete a transaction on acceptable terms, or at all. If we do not execute a strategic partnership transaction in the near term, it would eliminate a potential source of near-term funding, and may impact our ability to raise additional funds to meet our business needs. In addition, there are significant risks involved with building and managing a commercial infrastructure on a stand-alone basis, which could materialize in the event we do not execute a strategic partnership transaction or depending on the geographic scope of any executed transaction.

Interim, initial, top-line and preliminary data from our clinical trials that we announce 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 may publicly disclose preliminary, interim, or top-line data from our preclinical studies and clinical trials, which are based on preliminary analyses of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available or as patients from our clinical trials continue other treatments for their disease, or as inclusion and exclusion criteria is discussed with regulators. We also may make assumptions, estimations, calculations, and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the interim, top-line, or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data has been received and fully evaluated. Top-line data also remains 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, top-line data should be viewed with caution until the final data are available. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects. Further, disclosure of interim data by us or by our competitors could result in volatility in the price of our common stock.

In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is typically selected from a more extensive amount of available information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure. If the interim, top-line, or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

Our clinical trials may not be initiated or completed when we expect, or at all, may take longer and cost more to complete than we project, and may have higher costs than for more conventional therapeutic technologies or drug products. We may be required to conduct additional clinical trials or modify current or future clinical trials based on feedback we receive from the FDA.

We cannot guarantee that any current or future clinical trials will be conducted as planned or completed on schedule, if at all, or that any of our other product candidates will receive regulatory approval. A failure of one or more clinical trials can occur at any stage of the clinical trial process, other events may cause us to stop a clinical trial temporarily or permanently, and our future clinical trials may not be successful.

Because our current product candidates include, and we expect our future product candidates to include, candidates based on advanced therapy technologies, we expect that they will require extensive research and development and have substantial manufacturing costs. In addition, costs to treat patients and to treat potential side effects that may result from our product candidates can be significant. Some clinical trial sites may not bill, or obtain coverage from Medicare, Medicaid, or other third-party payors for some or all of these costs for patients enrolled in our clinical trials, and clinical trial sites outside of the U.S. may not reimburse for costs typically covered by third-party payors in the U.S. As a result, we may be required by those trial sites to pay such costs. Accordingly, our clinical trial costs are likely to be significantly higher per patient than those of more conventional therapeutic technologies or drug products.

Collaborations with other entities may be subject to additional delays because of the management of the trials, contract negotiations, the need to obtain agreement from multiple parties, and the necessity of obtaining additional approvals for therapeutics used in the combination trials. These combination therapies will require additional testing, and clinical trials will require additional FDA approval and will increase our future costs.

Any inability to successfully complete preclinical and clinical development could result in additional costs to us, slow down our product development and approval process, or impair our ability to commence product sales and generate revenues. In addition, if we make manufacturing changes to our approved product or other product candidates, we may be required to, or we may elect to, conduct additional trials to bridge our modified approved product or other product candidates to earlier versions. These changes may require FDA approval or notification and may not have their desired effect. The FDA may also not accept data from prior versions of the product to support an application, delaying our clinical trials or programs or necessitating additional clinical trials or preclinical studies. We may find that this change has unintended consequences that necessitate additional development and manufacturing work, additional clinical and preclinical studies, or that results in refusal to file or non-approval of a BLA and/or NDA.

Clinical trial delays could shorten any period during which our product candidates have patent protection and may allow our competitors to bring products to market before we do, which could impair our ability to successfully commercialize our product candidates and may harm our business and results of operations. In addition, we have in the past experienced clinical holds imposed upon certain of our or investigator-led clinical trials for various reasons, and we may experience further clinical trial holds in the future. If we fail to commence or complete, or experience delays in, any of our planned clinical trials, our stock price and our ability to conduct our business as currently planned could be harmed.

If we are required by the FDA or any equivalent foreign regulatory authority to perform clinical trials or studies in addition to those we currently expect to conduct, or if there are any delays in completing the clinical trials of our other product candidates, our expenses could increase substantially. On April 22, 2024, the FDA approved our product, ANKTIVA with BCG for the treatment of adult patients with BCG-unresponsive NMIBC with CIS with or without papillary tumors. We are required to comply with certain post-marketing commitments, including completion of our QUILT 3032 clinical trial and annual reporting for up to four years, with a final report submission to the FDA by the end of 2029.

Even if more of our product candidates are approved and commercialized, we still may not become profitable.

If approved for marketing by applicable regulatory authorities, our ability to generate revenues from our other product candidates will depend on our ability to:

- price our other product candidates competitively such that third-party and government reimbursement leads to broad product adoption;
- prepare a broad network of clinical sites for administration of our other product candidates;
- create market demand for our other product candidates through our own or our partner's marketing and sales activities, and any other arrangements to promote these product candidates that we may otherwise establish;
- receive regulatory approval for the targeted patient population(s) and claims that are necessary or desirable for successful marketing;
- manufacture our other product candidates through third-party CMOs or in our own manufacturing facilities or facilities owned by entities affiliated with Dr. Soon-Shiong in sufficient quantities and at acceptable quality and manufacturing cost to meet regulatory requirements and commercial demand at launch and thereafter;

- establish and maintain agreements with wholesalers, distributors, pharmacies, and group purchasing organizations on commercially reasonable terms;
- obtain, maintain, protect, and enforce patent and other intellectual property protection and regulatory exclusivity for our other product candidates;
- successfully commercialize any of our other product candidates that receive regulatory approval;
- maintain compliance with applicable laws, regulations, and guidance specific to commercialization including interactions with health care professionals, patient advocacy groups, and communication of health care economic information to payors and formularies;
- achieve market acceptance of our other product candidates by patients, the medical community, and third-party payors;
- achieve appropriate reimbursement for our product candidates;
- maintain a distribution and logistics network capable of product storage within our specifications and regulatory guidelines, and further capable of timely product delivery to commercial clinical sites;
- effectively compete with other therapies or competitors; and
- following launch, ensure that our approved product will be used as directed and that additional unexpected safety risks will not arise.

We can provide no assurance with respect to the profitability or the market share that we might achieve for our product candidates, if approved. The target patient population for which we obtain approval may be narrower than we expect. Additionally, we may not be able to obtain the labeling claims necessary or desirable for the promotion of our approved product. Further, supply chain issues or shortages associated with combination products that may be used with our approved product, such as ANKTIVA plus BCG, may limit the demand for our approved product.

We are also party to agreements that may require substantial payments upon the occurrence of certain milestones. As an example, in connection with our 2017 acquisition of Altor, we issued CVRs under which we agreed to pay the prior stockholders of Altor approximately $304.0 million of contingent consideration upon calendar-year worldwide net sales of ANKTIVA exceeding $1.0 billion prior to December 31, 2026 with amounts payable in cash or shares of our common stock or a combination thereof. As of December 31, 2024, Dr. Soon-Shiong and his related party hold approximately $139.8 million of net sales CVRs, and they have both irrevocably agreed to receive shares of the company's common stock in satisfaction of their CVRs. We may be required to pay the other prior Altor stockholders up to $164.2 million for their net sales CVRs should they choose to have their CVRs paid in cash instead of common stock. If this were to occur, we may need to seek additional sources of capital, and any such financing activities may be restricted by the covenants included in the terms of the RIPA. As such, we may face difficulties raising additional capital and may have to accept unfavorable terms and as a result, we may not be able to achieve profitability or positive cash flow.

In connection with our financing in December 2023, we entered into the RIPA with Infinity and Oberland. Oberland has the right to receive quarterly Revenue Interest Payments from us based on, among other things, our worldwide net sales, excluding those in China, which are tiered payments ranging from 4.50% to 10.00%, subject to increase or decrease, following the Test Date depending on whether our aggregate payments made to Oberland as of the Test Date have met or exceeded the Cumulative Purchaser Payments. In addition, if our aggregate payments made as of the Test Date to Oberland do not equal or exceed the amount of the Cumulative Purchaser Payments as of such date, then we are obligated to make a one-time payment True-Up Payment as described above. In addition to other considerations of the RIPA and the associated impact to our profitability and cash flow, if we were required to make a True-Up Payment, we may need to seek additional sources of capital, and we may not be able to achieve profitability or positive cash flow.

If we encounter delays or difficulties enrolling and/or maintaining patients in our clinical trials, our clinical development activities, and receipt of necessary marketing approvals, could be delayed or otherwise adversely affected.

The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the trial until its conclusion. We may experience difficulties or delays in patient enrollment and retention in our clinical trials for a variety of reasons.

Because the number of qualified clinical investigators is limited, we may need to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such clinical trial sites. In addition, in the past we have engaged, and we intend to continue to engage, in clinical trial efforts outside of the U.S., which gives rise to additional potential complexity and challenges, and further reliance upon third parties in foreign jurisdictions. Moreover, because our product candidates represent a departure from more commonly used methods for cancer and/or viral disease treatment, potential patients and their doctors may be inclined to use conventional therapies, such as chemotherapy and approved immunotherapies that have established safety and efficacy profiles, rather than enroll patients in any future clinical trial.

Delays or failures in planned patient enrollment or retention may result in increased costs or may affect the timing or outcome of the planned clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our product candidates or could render further development impossible.

Our approved product and other product candidates may cause undesirable side effects, adverse events, or have other properties or safety risks that could halt their clinical development, delay or prevent their regulatory approval, result in regulatory warning letters, product recalls, regulatory and manufacturing holds, or limit their commercial potential or result in other significant negative consequences.

Results of our trials could reveal a high and unacceptable severity and prevalence of side effects, adverse events or unexpected characteristics. Combination immunotherapy that includes our current product candidates may be associated with more frequent adverse events or additional adverse events. Undesirable side effects or unacceptable toxicities caused by our other product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials or order our clinical trials to be placed on clinical hold, and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other regulatory authorities for any or all targeted indications. The FDA or comparable foreign regulatory authorities may also require additional data, clinical trials, or preclinical studies should unacceptable toxicities arise. We may need to abandon development or limit development of that product candidate to certain 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. Even if we were to receive product approval, such approval could be contingent on inclusion of unfavorable information in our product labeling, such as limitations on the indicated uses for which the products may be marketed or distributed, a label with significant safety warnings, including boxed warnings, contraindications, and precautions, a label without statements necessary or desirable for successful commercialization, or requirements for costly post marketing testing and surveillance, or other requirements, including a REMS to monitor the safety or efficacy of the products, and in turn prevent us from commercializing and generating revenues from the sale of our current or future product candidates. In addition, these serious adverse effects may not be appropriately recognized or managed by the treating medical staff, as toxicities resulting from our other product candidates are not normally encountered in the general patient population and by medical personnel. They may have difficulty observing patients and treating toxicities, which may be more challenging due to personnel changes, shift changes, house staff coverage or related issues. This could lead to more severe or prolonged toxicities or even patient deaths, which could result in us or the FDA delaying, suspending or terminating one or more of our clinical trials and which could jeopardize regulatory approval. Any of these occurrences may materially harm our business, financial condition and prospects.

The manufacture of our approved product and other product candidates is complex, and we may encounter difficulties in production, particularly with respect to process development, quality control, cGMP compliance, or scaling-up of our manufacturing capabilities. If we or our related parties, or any of our third-party manufacturers, encounter such difficulties, our ability to gain approval, or to provide adequate supply of our product candidates for clinical trials or our products for patients, if approved, could be delayed or stopped, or we may be unable to maintain a commercially viable cost structure.

The manufacture of our approved product and other product candidates involves complex processes, especially for our biologics, vectors and cell therapy product candidates, which are complex, highly regulated and subject to multiple risks. As a result of the complexities, the cost to manufacture biologics, vectors, and cell therapies is generally higher than traditional small molecule chemical compounds, and the manufacturing process is less reliable and is more difficult to reproduce. The manufacture

of fusion proteins, DNA and vaccine vectors, and cell therapy products require significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of cell therapy products often encounter difficulties in production, particularly in scaling up initial production. These problems include difficulties with production costs and yields, quality control, including stability of the product or other product candidates and quality assurance testing, shortages of qualified personnel, and compliance with strictly enforced federal, state, local, and foreign regulations. We may also find that the manufacture of our approved product or other product candidates is more difficult than anticipated, resulting in an inability to produce a sufficient amount of our other product candidates for our clinical trials or, if approved, commercial supply. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects, and other supply disruptions. Our approved product and other product candidates are manufactured using processes developed or modified by us, our affiliates, or by our third-party collaborators that we may not utilize for more advanced clinical trials or commercialization.

Currently we manufacture our approved product and other product candidates in our own manufacturing facilities, facilities owned by entities affiliated with Dr. Soon-Shiong and/or through third-party CMOs. Our clinical trials will need to be conducted with product candidates and materials that were produced under cGMP and/or GTP regulations, which are enforced by regulatory authorities. Our approved product and other product candidates may compete with other products and product candidates for access to manufacturing facilities. Moreover, because of the complexity and novelty of our manufacturing process, there are only a limited number of manufacturers that operate under cGMP regulations and that are both capable of manufacturing our approved product and other product candidates for us and willing to do so. If our third-party CMOs cease manufacturing for us, we would experience delays in obtaining sufficient quantities of our approved product for commercial supply and other product candidates for clinical trials and, if approved, commercial supply of such future products. Further, our third-party CMOs may breach, terminate, or not renew our agreements with them. If we were to need to find alternative manufacturing facilities or transfer between existing facilities it may take us significant time to find a replacement, if we are able to find a replacement at all and it would significantly impact our ability to develop, obtain regulatory approval for or market our approved product and/or other product candidates, if approved. The commercial terms of any new arrangement could be less favorable than our existing arrangements and the expenses relating to the transfer of necessary technology and processes could be significant.

We and our suppliers and third-party CMOs must maintain compliance with cGMP requirements and other applicable regulatory requirements. Any failure to comply with these regulations may require us to cease sales of our approved product or repeat clinical trials, which would delay the regulatory review process of our other product candidates. We may not be able to demonstrate sufficient comparability between products manufactured in different runs at the same or at different facilities to allow for inclusion of the clinical results from patients treated with products from these different runs, in our product registrations or to ensure a cGMP process to qualify our other product candidates.

We also are required to register certain clinical trials and post the results of certain completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within specified timeframes. Failure to do so could result in enforcement actions and adverse publicity.

Reliance on third-party manufacturers entails exposure to risks to which we would not be subject if we manufactured the product candidate ourselves, including:

- inability to negotiate manufacturing and quality agreements with third parties under commercially reasonable terms;
- reduced day-to-day control over the manufacturing process for our other product candidates as a result of using third-party manufacturers for all aspects of manufacturing activities;
- reduced control over the protection of our trade secrets, know-how, and other proprietary information from misappropriation or inadvertent disclosure or from being used in such a way as to expose us to potential litigation;
- termination or non-renewal of manufacturing agreements with third parties in a manner or at a time that may be costly or damaging to us or result in delays in the development or commercialization of our approved product or other product candidates; and
- disruptions to the operations of our third-party manufacturers or suppliers caused by conditions unrelated to our business or operations, including the bankruptcy or personnel turnover at the manufacturer or supplier.

Moreover, any problems or delays we or our third-party CMOs experience in preparing for commercial scale manufacturing of a product candidate may result in a delay in the FDA approval of the product candidate or may impair our ability to manufacture commercial quantities or such quantities at an acceptable cost, which could result in the delay, prevention, or impairment of clinical development and commercialization of our product candidates and could adversely affect our business. Furthermore, if we or our third-party CMOs fail to deliver the required commercial quantities of our product candidates on a timely basis and at reasonable costs, we would likely be unable to meet demand for our products and we would lose potential revenues. We may ultimately be unable to reduce the cost of goods for our other product candidates to levels that will allow for an attractive return on investment if and when those product candidates are commercialized.

In addition, the manufacturing process and facilities for our approved product and any other products that we may develop are subject to FDA and foreign regulatory authority approval processes, and we or our third-party CMOs will need to meet all applicable FDA and foreign regulatory authority requirements, including cGMP, on an ongoing basis. cGMP requirements include quality control, quality assurance and the maintenance of records and documentation. The FDA and other regulatory authorities enforce these requirements through facility inspections. Manufacturing facilities must submit to pre-approval inspections by the FDA that will be conducted after we submit our marketing applications, including BLAs and NDAs, to the FDA. Manufacturers are also subject to continuing FDA and other regulatory authority inspections following marketing approval. Further, we and our third-party CMOs must supply all necessary CMC documentation in support of a BLA or NDA on a timely basis. Our or our third-party CMOs' manufacturing facilities may be unable to comply with our specifications, cGMP, and with other FDA, state, and foreign regulatory requirements, and there is no guarantee that we or our third-party CMOs will be able to successfully pass all aspects of a pre-approval or continued inspection by the FDA or other foreign regulatory authorities. For example, on May 9, 2023 the FDA delivered a CRL to us regarding the BLA filed in May 2022, indicating that the FDA had determined that it could not approve the original BLA submission in its initial form, and the FDA made recommendations to address the issues raised. The deficiencies in the CRL related to the FDA's pre-license inspection of the company's third-party CMOs, among other items. The CRL we received in response to our initial BLA submission required us to resubmit the BLA to the FDA addressing the issues in the CRL, resulting in additional expense and delay. On April 22, 2024, the FDA approved ANKTIVA with BCG for the treatment of adult patients with BCG-unresponsive NMIBC with CIS with or without papillary tumors.

Poor control of production processes can lead to the introduction of adventitious agents or other contaminants, or to inadvertent changes in the properties or stability of our product or other product candidates that may not be detectable in final product testing. If microbial, viral, environmental, or other contaminants are discovered in our product or other product candidates or in the manufacturing facilities in which our product or other product candidates are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination which could delay commercial sales and clinical trials and adversely harm our business. If we or our third-party CMOs are unable to reliably produce products to specifications acceptable to the FDA or other regulatory authorities, or in accordance with the strict regulatory requirements, we may not obtain or maintain the initial or continued approvals we need to commercialize such products. There is no assurance that either we or our third-party CMOs will be able to manufacture our approved product or any subsequently approved product candidate to specifications acceptable to the FDA or other regulatory authorities, to produce our product or other product candidates in sufficient quantities to meet the requirements for the launch of such products, or to meet potential future demand.

Deviations from manufacturing requirements may further require remedial measures that may be costly and/or time-consuming for us or a third party to implement and may include the temporary or permanent suspension of a clinical trial or commercial sales or the temporary or permanent closure of a facility. Any such remedial measures imposed upon us or third parties with whom we contract could materially harm our business.

As product candidates progress through preclinical and clinical trials to marketing approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize yield and manufacturing batch size, minimize costs and achieve consistent quality and results. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause our product or other product candidates to perform differently and affect our commercial sales or the results of planned clinical trials or other future clinical trials conducted with the altered materials. This could cause commercial sales to cease, delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates, and jeopardize our ability to commercialize our other product candidates, if approved, and generate revenues.

To the extent we use third-party CMOs, we are ultimately responsible for the manufacture of our products, once approved, and our other product candidates. A failure to comply with these requirements may result in regulatory enforcement actions against our manufacturers or us, including fines and civil and criminal penalties, which could result in imprisonment, suspension or restrictions of production, injunctions, delay or denial of product approval or supplements to approved products, clinical holds or termination of clinical trials, warning or untitled letters, regulatory authority communications warning the public about safety issues with the biologic, refusal to permit the import or export of the products, product seizure, detention, or recall, operating restrictions, suits under the federal civil FCA, corporate integrity agreements, consent decrees, or withdrawal of product approval.

Any of these challenges could cause us to cease commercial sales, delay completion of clinical trials, require bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidate, impair commercialization efforts, increase our cost of goods, and have a material adverse effect on our business, financial condition, results of operations and growth prospects.

We may not be successful in managing the buildout of our manufacturing facilities and associated costs or satisfying manufacturing-related regulatory requirements.

We have entered into facility leases for our planned manufacturing operations and related activities under which we are responsible for the buildout of the facility space and associated costs. The buildout of these facilities and related equipment purchases are complex and specialized and will involve substantial capital expenditures, and it could take longer, and cost more, than currently expected. Significant delays and/or cost overruns would result in higher expenditures and could be disruptive to operations, any of which could have a negative impact on our financial condition or results of operations. For example, during the first quarter of 2022 we acquired a leasehold interest in the 409,000 square foot Dunkirk Facility as described below. While we believe that governmental funding will assist in funding a small portion of the further buildout of the Dunkirk Facility, we will need to plan and fund most of the additional buildout of, and purchase additional equipment for, the Dunkirk Facility in connection with our planned full operations. In addition, it is possible that, once built, the leased facilities may prove to be less conducive to our operations than is currently anticipated, resulting in operational inefficiencies or similar difficulties that could prove difficult or impossible to remediate and result in an adverse impact on our financial condition or results of operations.

We also may not successfully realize the anticipated benefits from capital expenditures at such facilities based on factors such as delays and uncertainties regarding development, regulatory approval, and commercialization of our product candidates, as well as the potential to lose access to the leased facilities.

Further, in the future if we transition from our current third-party CMOs to our own manufacturing facilities, or to alternative third-party CMOs, for one or more of our products or other product candidates, including our approved product, we will need to conduct additional preclinical, analytical and/or clinical testing and obtain FDA approval before such manufacturing changes are implemented. If we are unsuccessful in demonstrating the comparability of supplies before and after a manufacturing change, such manufacturing change can result in a delay or disruption in our clinical development plan or our ability to commercialize any approved product. Any production shortfall that impairs the supply of our product or other product candidates could negatively impact our ability to sell our approved product, complete clinical trials, obtain regulatory approval, and commercialize our other product candidates. A product shortfall could have a material adverse effect on our business, financial condition and results of operations and adversely affect our ability to satisfy demand for our product or other product candidates, which could materially and adversely affect our revenue and results of operations.

In addition, our planned operations, including our development, testing, and future manufacturing activities, are subject to numerous environmental, health, and safety laws and regulations. These laws and regulations govern, among other things, the controlled use, handling, release, and disposal of and the maintenance of a registry for, hazardous materials and biological materials, such as chemical solvents, human cells, carcinogenic compounds, mutagenic compounds, and compounds that may have a toxic effect on reproduction, laboratory procedures and exposure to blood-borne pathogens. If we fail to comply with such laws and regulations, we could be subject to fines or other sanctions. Failure to successfully complete our buildouts and successfully operate our planned manufacturing facilities and satisfy manufacturing-related regulatory requirements could adversely affect the commercial viability of our product candidates and our business.

Cell-based therapies and biologics rely on the availability of reagents, specialized equipment, and other specialty materials, which may not be available to us on acceptable terms or at all. For some of these reagents, equipment, and materials, we rely or may rely on sole source vendors or a limited number of vendors, which could impair our ability to manufacture and supply our approved product and any future products, if approved.

We currently depend on a small number of suppliers for some of the materials used in, and processes required to develop, our approved product and other product candidates. For some of these reagents, equipment, and materials used in the manufacture of our approved product and other product candidates, we rely and may in the future rely on sole source vendors or a limited number of vendors. Some of these suppliers may not have the capacity to support commercial scale or clinical trials and commercial products manufactured under cGMP by biopharmaceutical firms or may otherwise be ill-equipped to support our needs. We also do not have supply contracts with many of these suppliers and may not be able to obtain supply contracts with them on acceptable terms or at all. Accordingly, we may experience delays in receiving key materials and equipment to support clinical or commercial manufacturing. An inability to continue to source product from any of these suppliers could adversely affect our ability to satisfy demand for our approved product and other product candidates, which could adversely and materially affect our product sales and operating results or our ability to conduct clinical trials, either of which could significantly harm our business.

As we seek to develop and scale our manufacturing process, we expect that we will need to obtain rights to and supplies of certain materials and equipment to be used as part of that process. We may not be able to obtain rights to such materials on commercially reasonable terms, or at all, and if we are unable to alter our process in a commercially viable manner to avoid the use of such materials or find a suitable substitute, it would have a material adverse effect on our business. Even if we are able to alter our process so as to use other materials or equipment, such a change may lead to a delay in our clinical development and/or commercialization plans. If such a change occurs for a product candidate that is already in clinical testing, the change may require us to perform both *ex vivo* comparability studies and to collect additional data from patients prior to undertaking more advanced clinical trials.

Because our approved product and other product candidates represent, and our other potential product candidates will represent, novel approaches to the treatment of disease, there are many uncertainties regarding the development, market acceptance, public opinion, third-party reimbursement coverage, and the commercial potential of our approved product and other product candidates, which may impact public perception of us and our approved product and other product candidates and which may adversely affect our ability to conduct our business and implement our business plans.

Human immunotherapy products are a new category of therapeutics. We use relatively novel technologies involving ANKTIVA, hAd5 and yeast constructs, and cell-based therapies, and our NK cell platform utilizes a relatively novel technology involving the genetic modification of human cells and utilization of those modified cells in other individuals. Because this is a relatively new and expanding area of novel therapeutic interventions, there are many uncertainties related to development, marketing, reimbursement, and the commercial potential for our approved product and other product candidates. There can be no assurance as to the length of the trial period, the number of patients the FDA will require to be enrolled in the trials in order to establish the safety, efficacy, purity and potency of immunotherapy products, or that the data generated in these trials will be acceptable to the FDA to support marketing approval. Adverse public attitudes may adversely impact our ability to enroll patients in clinical trials. The FDA may take longer than usual to come to a decision on any BLA and/or NDA that we submit and may ultimately determine that there is not enough data, information, or experience with our product candidates to support an approval decision. The FDA may also require that we conduct additional post-marketing studies or implement risk management programs, such as REMS, until more experience with our other product candidates is obtained. Finally, after increased usage, we may find that our product or other product candidates do not have the intended effect, do not work with other combination therapies or have unanticipated side effects, potentially jeopardizing initial or continuing regulatory approval and commercial prospects. More restrictive government regulations or negative public opinion could have an adverse effect on our business or financial condition and may delay or impair the commercialization of our approved product and development and commercialization of our product candidates or demand for our product or any products we may develop. Adverse events in our clinical trials, even if not ultimately attributable to our product candidates, and the resulting publicity could result in increased governmental regulation, unfavorable public perception, potential regulatory delays in the testing or approval of our potential product candidates, stricter labeling requirements for those product candidates that are approved and a decrease in demand for any such product candidates.

There is no assurance that the approaches offered by our approved product or other product candidates will gain broad acceptance among doctors or patients or that governmental agencies or third-party medical insurers will be willing to provide reimbursement coverage for our proposed product candidates. Public perception may be influenced by claims, such as claims that our technologies are unsafe, unethical or immoral and, consequently, our approach may not gain the acceptance of the public or the medical community. Negative public reaction to cell-based immunotherapy in general could result in greater government regulation and stricter labeling requirements of immunotherapy products, including our other product candidates, and could cause a decrease in the demand for our approved product and any other products we may develop. Moreover, our success will depend upon physicians specializing in the treatment of those diseases that our product or other product candidates target prescribing, and their patients being willing to receive treatments that involve the use of our product or other product candidates in lieu of, or in addition to, existing treatments they are already familiar with and for which greater clinical data may be available. The market for any products that we successfully develop will also depend on the cost of the products. Our goal is to reduce the cost of manufacturing and providing our therapies. However, unless we can reduce those costs to an acceptable amount, we may never be able to develop a commercially viable product. If we do not successfully develop and commercialize products based upon our approach or find suitable and economical sources for materials used in the production of our product or potential products, we will not become profitable, which would materially and adversely affect the value of our common stock. Our ANKTIVA therapies and our other therapies may be provided to patients in combination with other agents provided by third parties or our affiliates. The cost of such combination therapy may increase the overall cost of therapy and may result in issues regarding the allocation of reimbursements between our therapy and the other agents, all of which may affect our ability to obtain reimbursement coverage for the combination therapy from governmental or private third-party medical insurers.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our approved product or other product candidates.

We face an inherent risk of product liability as a result of the commercialization of our approved product and clinical development, testing and manufacturing of our other product candidates. For example, we may be sued if our approved product or other product candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claim may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability, or a breach of warranties. Claims could also be asserted under state consumer protection acts. Large judgments have been awarded in class action lawsuits based on therapeutics that had unanticipated side effects. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our approved product or other product candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in a regulatory investigation of the safety and effectiveness of our products, our third-party manufacturer's manufacturing processes and facilities or our marketing programs and potentially a recall of our products or more serious enforcement action, including limitations on the approved indications for which our product candidates may be used or suspension or withdrawal of approvals, 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 trial participants or patients and a decline in our stock price.

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

We will face significant competition from other biotechnology and pharmaceutical companies and from non-profit institutions.

Competition in the field of cancer and infectious disease therapy is intense and is accentuated by the rapid pace of technological development. We compete with a variety of multi-national biopharmaceutical companies and specialized biotechnology companies, as well as technology being developed at universities and other research institutions. These competitors have developed, may develop, and are developing product candidates and processes competitive with our approved product or other product candidates. Research and discoveries by others may result in breakthroughs which may render our approved product

or other product candidates obsolete even before they generate any revenues. We believe that a significant number of products are currently under development, and may become commercially available in the future, for the treatment of conditions for which our product treats or for which we are developing product candidates. Many of our competitors have several therapeutic products that have already been developed, approved and successfully commercialized, or are in the process of obtaining regulatory approval for their therapeutic products in the U.S. and internationally. Many of our competitors, either alone or with their strategic partners, have substantially greater financial, technical, and human resources than we do, as well as significantly greater experience in the discovery and development of product candidates, obtaining FDA and other regulatory approvals of treatments and commercializing those treatments. Accordingly, our competitors may be more successful in obtaining approval of treatments and achieving widespread market acceptance, rendering our treatments obsolete or non-competitive, possibly even before we are able to enter the market. Accelerated merger and acquisition activity in the biotechnology and biopharmaceutical industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties 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.

The availability and price of our competitors' products could limit the demand and the price we are able to charge for our approved product or any of our other product candidates, if approved. The level of generic competition and the availability of reimbursement from government and other third-party payors will also significantly affect the pricing and competitiveness of our products.

We may not be able to implement our business plan if the acceptance of our approved product or other product candidates is inhibited by price competition or the reluctance of physicians to switch from other methods of treatment to our approved product, or if physicians switch to other new therapies, drugs or biologic products or choose to reserve our products for use in limited circumstances. We may be adversely impacted if any of these competitors gain market share as a result of new technologies, commercialization strategies or otherwise.

We may seek orphan drug status or Breakthrough Therapy, Fast Track or RMAT designations or other designation from the FDA or comparable non-U.S. regulatory authorities for one or more of our product candidates, but even if any such designation or status is granted, it may not lead to a faster development process or regulatory review and may not increase the likelihood that our product candidates will receive marketing approval, and we may be subject to significant costs including those associated with EAPs, and be unable to maintain any benefits associated with such designations or status, including market exclusivity.

We have been awarded *Breakthrough Therapy, Fast Track* and RMAT designations, and may seek in the future such designations for current or future product candidates. Receipt of a designation to facilitate product candidate development is within the discretion of the FDA. Accordingly, even if we believe one of our product candidates meets the criteria for a designation, the FDA may disagree. 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. In any event, the receipt of such a designation for our product candidates may not result in a faster development process, review, or approval compared to product candidates considered for approval under conventional FDA procedures and does not ensure ultimate marketing approval by the FDA. In addition, the FDA may later decide that the product candidates no longer meet the designation conditions. See Item 1. "*Business—Government Regulation—BLA/NDA Submission and Review by the FDA*" for additional information regarding these designations. If granted, accelerated approval is usually contingent on the sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the drug's clinical benefit, and the FDA is permitted to require, as appropriate, that such studies be underway prior to approval or within a specified period after the date of approval. Sponsors must also update the FDA on the status of these studies, and the FDA has increased authority to withdraw approval of a drug granted accelerated approval on an expedited basis if the sponsor fails to conduct such studies in a timely manner, or send the necessary updates to the FDA, or if such post-approval studies fail to verify the drug's predicted clinical benefit. Prior to seeking accelerated approval, we will seek feedback from the FDA or comparable non-U.S. regulatory authorities and will otherwise evaluate our ability to seek and receive such 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. Similarly, there can be no assurance that after subsequent feedback from the FDA or comparable non-U.S. regulatory authorities, we will

continue to pursue or apply for accelerated approval or any other form of expedited development, review or approval, even if we initially decide to do so. Furthermore, if we decide to submit an application for accelerated approval, there can be no assurance that such application will be accepted or that any approval will be granted on a timely basis, or at all. The FDA or other comparable non-U.S. regulatory authorities could also require us to provide expensive investigational drug at non-commercial pricing or at no cost as part of a designation associated required EAP. For example, as part of our RMAT designation associated with lymphopenia and pancreatic cancer, we intend to submit an EAP for ANKTIVA and PD-L1 t-haNK in combination with standard-of-care chemotherapy/radiotherapy. The FDA or other comparable non-U.S. regulatory authorities could also require us to conduct further studies prior to considering our application or granting approval of any type, including, for example, if other products are approved via the accelerated pathway and subsequently converted by FDA to full approval. A failure to obtain accelerated approval or any other form of expedited development, review or approval for our product candidate would result in a longer time period to commercialization of such product candidate, could increase the cost of development of such product candidate, and could harm our competitive position in the marketplace. Moreover, even if we are able to obtain accelerated approval for any of our product candidates, there is no guarantee that post-approval studies will be able to confirm the clinical benefit, which could cause the FDA to withdraw our approval.

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition or for which there is no reasonable expectation that the cost of developing and making available the drug or biologic will be recovered from sales in the U.S. If a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications, including a full BLA to market the same drug or biologic for the same indication for seven years, except in limited circumstances. We may seek orphan drug status for one or more of our product candidates, but exclusive marketing rights in the U.S. may be lost if we seek approval for an indication broader than the orphan designated indication and may be lost if the FDA later determines that the request for designation was materially defective or if we are unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition. In response to *Catalyst Pharms., Inc. v. Becerra*, 14 F.4th 1299 (11th Cir. 2021), the FDA clarified in a January 2023 notice that it intends to continue to apply its longstanding interpretation of the regulations to matters outside of the scope of the *Catalyst* order – that is, the agency will continue tying the scope of orphan-drug exclusivity to the uses or indications for which a drug is approved, which permits other sponsors to obtain approval of a drug for new uses or indications within the same orphan designated disease or condition that have not yet been approved. It is unclear how future litigation, legislation, agency decisions, and administrative actions will impact the scope of the orphan drug exclusivity.

As a condition of approval, the FDA may require that we implement various post-marketing requirements and conduct post-marketing studies, any of which would require a substantial investment of time, effort, and money, and which may limit our commercial prospects.

As a condition of biologic licensing, the FDA is authorized to require that sponsors of approved BLAs implement various post-market requirements, including REMS and Phase 4 trials. In connection with the regulatory approval of ANKTIVA with BCG for the treatment of adult patients with BCG-unresponsive NMIBC with CIS with or without papillary tumors, we are required to comply with certain post-marketing commitments, including completion of our QUILT 3032 clinical trial and annual reporting for up to four years, with a final report submission to the FDA by the end of 2029. If we receive approval of our other product candidates, the FDA may determine that similar or additional or more burdensome post-approval requirements are necessary to ensure that our product candidates are safe, pure and potent. For example, in connection with FDA approval of another company's drug, the FDA required significant post-marketing commitments, including a Phase 4 trial, revalidation of a test method, and a substantial REMS program that included, among other requirements, the certification of hospitals and their associated clinics that dispensed the drug, including the implementation of a training program and limited distribution only to certified hospitals and their associated clinics. To the extent that we are required to establish and implement any post-approval requirements, we will likely need to invest a significant amount of time, effort and money. Such post-approval requirements may also limit the commercial prospects of our product candidates.

We have never commercialized a product candidate before our approved product, and we may lack the necessary expertise, personnel and resources to successfully commercialize any products on our own or together with suitable collaborators. We may be unable to establish effective marketing and sales capabilities or enter into agreements with third parties or related parties to market and sell our other product candidates, if they are approved, and as a result, we may be unable to generate product revenues.

We have little to no prior experience in the marketing, sale and distribution of biopharmaceutical products. To achieve commercial success for our approved product and other product candidates, which we may license to others, we may rely on the assistance and guidance of those collaborators. In order to commercialize our approved product and our other product candidates for which we retain commercialization rights and marketing approval, if approved, we must continue to build out our marketing, sales and distribution capabilities, including a comprehensive healthcare compliance program, and/or arrange with third parties to perform these services, which will continue to take time and require significant financial expenditures, and could delay any product launch and we may not be successful in doing so. There are significant risks involved with building and managing a commercial infrastructure. We, our collaborators and third-party contractors, have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train, manage and retain medical affairs, marketing, sales and commercial support personnel. Recruiting, training, and retaining a sales force is expensive and time-consuming and could delay any product launch. If the commercial launch of our approved product or any other product candidate for which we or our third-party contractors recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have incurred these commercialization expenses prematurely or unnecessarily. These efforts may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel. In the event we are unable to develop a commercial infrastructure, we may not be able to commercialize our current or future product candidates, which would limit our ability to generate product revenues. Even if we and/or our potential partners and/or third-party contractors are able to effectively establish a sales force and develop a marketing and sales infrastructure, such sales force and marketing teams may not be successful in commercializing our approved product or any other current or future product candidates. To the extent we rely on third parties to commercialize any products for which we obtain regulatory approval, which we are doing to a certain extent in connection with our approved product launch, we may have less control over their sales efforts and could be held liable if they failed to comply with applicable legal or regulatory requirements.

If our approved product or any of our other product candidates do not achieve broad market acceptance, the revenues that we generate from their sales will be limited.

We are in the process of commercializing our approved product. Our approved product and other product candidates, if approved by the appropriate regulatory authorities for marketing and sale, may not gain acceptance among physicians, patients, third-party payors, and others in the medical community. If our approved product or any other product candidate for which we obtain regulatory approval does not gain an adequate level of market acceptance, we may not generate significant product revenues or become profitable. Market acceptance of our approved product or any other product candidates by the medical community, patients and third-party payors will depend on a number of factors, some of which are beyond our control. For example, physicians are often reluctant to switch their patients, and patients may be reluctant to switch from existing therapies even when new and potentially more effective or safer treatments enter the market. Efforts to educate the medical community and third-party payors on the benefits of our approved product and other product candidates may require significant resources and may not be successful. Even if the medical community accepts that our approved product and other product candidates are safe and effective for their approved indications, physicians and patients may not immediately be receptive to such approved product or other product candidates and may be slow to adopt them as an accepted treatment of the approved indications, including, for example, if third-party payors require high co-payments or if physicians perceive that reimbursement will not be available on a timely basis or at all. If our product or any of our other product candidates is approved but does not achieve an adequate level of market acceptance, we may not generate significant revenues and we may not become profitable. The degree of market acceptance of our approved product or any of our other product candidates will depend on a number of factors, including:

- the continued safety and efficacy of our approved product or other product candidates;
- the prevalence and severity of adverse events associated with such approved product or other product candidates;
- the clinical indications for which the products are approved and the approved claims that we may make for the products;
- limitations or warnings contained in the product's FDA-approved labeling, including potential limitations or warnings for such products that may be more restrictive than other competitive products or distribution and use restrictions imposed by the FDA with respect to such approved product or other product candidates or to which we agree as part of a mandatory REMS or voluntary risk management plan;

- changes in the standard-of-care for the targeted indications for such approved product or other product candidates;
- the relative difficulty of administration of our approved product or other product candidates;
- our ability to offer our approved product or other product candidates for sale at competitive prices, including the cost of treatment vs. economic and clinical benefit in relation to alternative treatments or therapies;
- the availability of adequate coverage or reimbursement by third parties, such as insurance companies and other healthcare payors, and by government healthcare programs, including Medicare and Medicaid;
- the extent and strength of our marketing and distribution of such approved product or other product candidates;
- the safety, efficacy and other potential advantages over, and availability of, alternative treatments already used or that may later be approved for any of our intended indications;
- the timing of market introduction of our approved product or other product candidates, as well as competitive products;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the extent and strength of our third-party manufacturer and supplier support;
- adverse publicity about the product or favorable publicity about competitive products; and
- potential product liability claims.

If our approved product or any other product candidate that we commercialize fails to achieve market acceptance, it could have a material and adverse effect on our business, financial condition, results of operations, and prospects.

Our approved product and our product candidates may face competition sooner than anticipated.

The enactment of the BPCIA created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. Under the BPCIA, the FDA cannot make an approval of an application for a biosimilar product effective until 12 years after the original branded product was approved under a BLA. Certain changes, however, and supplements to an approved BLA, and subsequent applications filed by the same sponsor, manufacturer, licensor, predecessor in interest or other related entity do not qualify for the 12-year exclusivity period.

Our approved product and/or product candidates may qualify for the BPCIA's 12-year period of exclusivity. There is a risk that any product candidates we may develop that are approved as a biological product under a BLA would not qualify for the 12-year period of exclusivity or that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider our approved product or any other product candidates we may develop to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Additionally, this period of regulatory exclusivity does not block companies pursuing regulatory approval via their own traditional BLA, rather than via the abbreviated pathway. Even if we receive a period of BPCIA exclusivity for our approved product, if subsequent products do not include a modification to the structure of the product that impacts safety, purity, or potency, we may not receive additional periods of exclusivity for those products. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of our reference product candidates 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. Medicare Part B encourages use of biosimilars by paying the provider the same percentage of the reference product average sale price as a mark-up, regardless of which product is reimbursed. It is also possible that payors will give reimbursement preference to biosimilars even over reference biologics absent a determination of interchangeability.

For our small molecular product candidates, if qualified, the regulatory exclusivity period is less than for our biologic product candidates. The FD&C Act provides a five-year period of non-patent marketing exclusivity within the U.S. to the first applicant to gain approval of an NDA for a drug where the FDA has not previously approved any other new drug containing the same active molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an abbreviated NDA or a 505(b)(2) NDA submitted by another company for a generic version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement. The FD&C Act also provides three years of marketing exclusivity for an NDA, 505(b)(2) NDA or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, which were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example, new indications, dosages or strengths of an existing drug. As such, we may face competition from generic versions of our small molecule product candidates, which will negatively impact our long-term business prospects and marketing opportunities.

We will need to obtain FDA approval of any proposed branded product names, and any failure or delay associated with such approval may adversely affect our business.

Any name we intend to use for our product candidates in the U.S. will require approval from the FDA regardless of whether we have secured a formal trademark registration from the USPTO. The FDA typically conducts a review of proposed product names, including an evaluation of the potential for confusion with other product names. The FDA may also object to a product name if it believes the name inappropriately implies medical claims or contributes to an overstatement of efficacy. If the FDA objects to any of our proposed product names, we may be required to adopt alternative names for our product candidates. If we adopt alternative names, we will lose the benefit of any existing trademark applications for such product candidate and may be required to expend significant additional resources in an effort to identify a suitable product name that would qualify under applicable trademark laws, not infringe or otherwise violate the existing rights of third parties, and be acceptable to the FDA. We may be unable to build a successful brand identity for a new product name in a timely manner or at all, which would limit our ability to commercialize our product candidates.

Our systems, infrastructure or data, or those used by our CROs, CMOs, clinical sites or other contractors or consultants, may fail or suffer a cyberattack, security breach or other incident, including a breakdown or compromise of the confidentiality, integrity and availability of our systems, networks or data, which could adversely affect the operation of our business and reputation.

We are and will be dependent upon information technology systems, infrastructure, and data. In the ordinary course of our business, we will directly or indirectly collect, store, transmit, and otherwise process sensitive and confidential information, including intellectual property, preclinical, and clinical trial data, proprietary business information, and personal information of our clinical trial patients and employees, including in our data centers and on our systems and networks or on those of third parties. The secure maintenance, transmission, and processing of data is critical to our operations. The multitude and complexity of our systems and those of our CROs, CMOs, clinical sites, or other contractors or consultants may subject them to various threats, including interruption, destruction, malicious intrusion, and random attack. Privacy or security breaches or other incidents, including by third parties, employees, contractors or others, may pose a risk that sensitive or confidential information, including our intellectual property, trade secrets or personal information of our employees, patients, or other business partners may be exposed to unauthorized persons or to the public. Further, as many of our employees work remotely, our reliance on our and third-party systems has increased substantially and is expected to continue to increase.

Despite the implementation of security measures, our systems, infrastructure and data, and those of our CROs, CMOs, clinical sites and other contractors and consultants, are subject to risks relating to cyberattacks, security breaches, or other incidents, including through viruses and other malware, employee error, unauthorized access, natural disasters, terrorism, war, fire, telecommunication and electrical failures, denial of service attacks, social engineering (including phishing attacks) and other means. As the cyberthreat landscape evolves, these cyberattacks are increasing in their frequency, sophistication and intensity and are becoming increasingly difficult to detect. The techniques used by cybercriminals change frequently, may not be recognized until launched and can originate from a wide variety of sources, including outside groups such as external service providers, organized crime affiliates, terrorist organizations or hostile foreign governments or agencies. Cyberattacks affect service reliability and threaten data confidentiality, integrity and availability. While we and our shared services partner, NantWorks, have

invested, and continue to invest, in the protection of our data, systems, and infrastructure, there can be no assurance that our efforts, or the efforts of our partners, vendors, CROs, CMOs, clinical sites and other contractors and consultants, will be successful. Any failure or perceived failure in our systems, infrastructure or data, or to identify or prevent cyberattacks, security breaches or other incidents, including service interruptions could adversely affect our business and operations, result in the loss, unavailability, misuse, unauthorized use or acquisition, or other unauthorized processing of critical or sensitive information, and result in financial, legal, business or reputational harm. In addition, our liability insurance may not be sufficient in type or amount to cover us against claims related to any such failures, security breaches, cyberattacks or other incidents.

If any such event were to occur, it could also cause interruptions in our operations, including a disruption of our product development programs. For example, the loss of clinical trial data from completed or ongoing clinical trials for a product candidate could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data or may limit our ability to effectively execute a product recall, if required. Any such event could result in liability, delays in the development and commercialization of product candidates, claims, demands or proceedings initiated by regulatory authorities or private parties, violations of laws, including laws that protect the privacy or security of personal information, significant liabilities, including regulatory penalties, damage to our reputation, and a loss of confidence in us and our ability to conduct clinical trials.

A pandemic, epidemic or outbreak of an infectious disease, such as COVID-19, or the perception of its effects, may materially and adversely affect our business, operations and financial condition.

Public health outbreaks, such as epidemics or pandemics may significantly disrupt our business. Such outbreaks pose the risk that we or our employees, contractors, suppliers, and other partners may be prevented from conducting business activities for an indefinite period of time due to the spread of the disease, due to shutdowns that may be requested or mandated by federal, state, and local governmental authorities or certain employers, or due to the economic consequences associated with the pandemic. Business disruptions could include disruptions or restrictions on our ability to travel, as well as temporary closures of our facilities and the facilities of our partners, clinical trial sites, service providers, suppliers, or CMOs. For example, the COVID-19 pandemic caused a temporary disruption in our ability to recruit participants for our clinical trials in the calendar year 2020 and the first quarter of 2021. While it is not possible to predict whether another pandemic, epidemic, or infectious disease outbreak similar to COVID-19 will materialize, any measures taken by governments and local authorities in response to such future health crises have the potential to disrupt and delay the initiation of new clinical trials, the progress of our ongoing clinical trials and our preclinical activities, and potentially the manufacture or shipment of both drug substance and finished drug product of our approved product and our other product candidates for preclinical testing and clinical trials, may adversely impact our business, financial condition, or operating results.

Risks Related to Reliance on Third Parties

We have relied and will continue to rely on third parties and related parties to conduct some of our preclinical studies and clinical trials, manufacture our approved product and other product candidates, and perform many essential services for any products that we commercialize, including services related to sales and marketing, distribution, government price reporting, customer service, accounts receivable management, cash collection and adverse event reporting. Any failure by a third party or related party to perform as expected, to comply with legal and regulatory requirements, to manufacture products in compliance with cGMP, or to conduct the clinical trials according to GCP guidelines, and in a timely manner, may delay or prevent our ability to commercialize our approved product, to seek or obtain regulatory approval for or commercialize our other product candidates or may subject us to regulatory sanctions.

We have relied and will continue to rely on third parties and related parties to conduct some of our preclinical studies and clinical trials, manufacture our approved product and other product candidates, and perform many essential services for our approved product and any products that we commercialize. Any failure by a third party or related party to perform as expected, to comply with legal and regulatory requirements, to manufacture products in compliance with cGMP, or to conduct the clinical trials according to GCP guidelines, and in a timely manner, may delay or prevent our ability to commercialize our approved product, to seek or obtain regulatory approval for or commercialize our other product candidates, or may subject us to regulatory sanctions.

Large-scale clinical trials require significant financial and management resources. We expect to be heavily reliant on third and related parties, including medical institutions, academic institutions, clinical investigators or CROs to conduct, supervise or monitor some or all aspects of our clinical trials, and in some cases, third-party CMOs to manufacture our approved product or other product candidates, which may force us to encounter delays and challenges that are outside of our control. Nevertheless, we are responsible for ensuring that each of our trials is conducted in accordance with the applicable trial protocol and legal, regulatory and scientific standards, and our reliance on CROs, clinical trial sites, and other third parties does not relieve us of these responsibilities. Our CROs and other third parties must communicate and coordinate with one another in order for our trials to be successful. We have a limited history of conducting clinical trials and have limited experience as a company in submitting and supporting the applications necessary to gain marketing approvals. Our relative lack of experience conducting clinical trials may contribute to our planned clinical trials not beginning or completing on time, if at all. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities and clinical trial sites by, applicable regulatory authorities.

For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial and for ensuring that our preclinical studies are conducted in accordance with GLP guidelines, as appropriate. Moreover, the FDA and comparable foreign regulatory authorities require us and the third parties upon which we intend to rely for conducting our clinical trials to comply with GCP guidelines for conducting, recording, and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity, and confidentiality of trial participants are protected. Regulatory authorities enforce these requirements through periodic inspections (including pre-approval inspections once a BLA or NDA is filed with the FDA) of trial sponsors, clinical investigators, trial sites, and certain third parties including CMOs. If we, our CROs, clinical trial sites, or other third parties fail to comply with applicable GCP guidelines or other regulatory requirements, we or they may be subject to enforcement or other legal actions, the clinical data generated in our clinical trials may be deemed unreliable and have to be repeated, and our submission of marketing applications may be delayed or the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP guidelines.

We rely on third parties to manufacture, package, label, and ship our approved product and some of our other product candidates for the clinical trials that we conduct. Any performance failure on the part of these third parties could delay commercialization of our approved product or other product candidates, or the clinical development or marketing approval of our product candidates producing additional losses and depriving us of potential product revenues.

Our CROs, clinical trial sites, and other third parties may also have relationships with other entities, some of which may be our competitors, for whom they may also be conducting clinical trials or other therapeutic development activities that could harm our competitive position. In addition, these third parties are not our employees, and except for remedies available to us under our agreements with them, we cannot control whether or not they devote sufficient time and resources to our ongoing clinical and preclinical programs. If these third parties conducting our clinical trials (i) do not successfully carry out their contractual duties, (ii) do not meet expected deadlines, (iii) experience work stoppages, (iv) do not conduct our clinical trials in accordance with regulatory requirements or our stated protocols, (v) need to be replaced, (vi) experience financial hardships, or (vii) terminate their agreements with us or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our clinical trial protocols, GCP guidelines, or other regulatory requirements or for other reasons, our trials may need to be repeated, extended, delayed, or terminated, we may not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates, we will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates, or we or they may be subject to regulatory enforcement actions. Additionally, we may need to conduct additional clinical trials or enter into new arrangements with alternative CROs, clinical investigators or other third parties, which we may not be able to do on commercially reasonable terms, or at all and which may involve additional cost and time and require management time and focus. As a result, delays could occur, which could compromise our ability to meet our desired development timelines. Furthermore, if any of the third parties conducting our clinical trials experience any financial hardships due to difficulties relating to the operation of their business, it could damage our business, financial condition, results of operations, and prospects. In addition, if an agreement with any of our collaborators terminates, our access to technology and intellectual property licensed to us by that collaborator may be restricted or terminate entirely, which may delay the continued development of our product candidates using the collaborator's technology or intellectual property or require us to stop development of those product candidates completely. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed. To the extent we are unable to successfully identify and manage the performance of third-party service providers in the future, our business may be materially and adversely affected.

We have and we expect to continue to retain third-party service providers to perform a variety of functions related to the sale of our approved product and current or future product candidates, key aspects of which will be out of our direct control. These service providers may provide key services related to sales, market access, distribution, customer service, accounts receivable management, state reporting, compliance support, and cash collection. If we retain a service provider, we will substantially rely on it as well as other third-party providers that perform services for us, including entrusting our inventories of products to their care and handling. If these third-party service providers fail to comply with applicable laws and regulations, fail to meet expected deadlines or otherwise do not carry out their contractual duties to us, or encounter physical or natural damage at their facilities, our ability to deliver product to meet commercial demand would be significantly impaired and we may be subject to regulatory enforcement action.

In addition, we may engage in the future with third parties to perform various other services for us relating to adverse event reporting, safety database management, fulfillment of requests for medical information regarding our product candidates, and related services. If the quality or accuracy of the data maintained by these service providers is insufficient, or these third parties otherwise fail to comply with regulatory requirements related to adverse event reporting, we could be subject to regulatory sanctions.

Additionally, we have contracted with one or more third parties to calculate and report pricing information mandated by various government programs and may enter into further contracts in the future. If a third party fails to timely report or adjust prices as required or makes a mistake in calculating government pricing information from transactional data in our financial records, it could impact our discount and rebate liabilities, and potentially subject us to regulatory sanctions or FCA lawsuits.

Our reliance on third and related parties can also present intellectual property-related risks. For example, collaborators may not properly obtain, maintain, enforce or defend intellectual property or proprietary rights relating to our product candidates or technology or may use our proprietary information in such a way as to expose us to potential litigation or other intellectual property-related proceedings, including proceedings challenging the scope, ownership, validity and enforceability of our intellectual property. Collaborators may also own or co-own intellectual property covering our product candidates or technology that results from our collaboration with them, and in such cases, we may not have the exclusive right to commercialize such intellectual property or such product candidates or technology. Collaborators may also gain access to our trade secrets or formulations and impact our ability to commercialize our proprietary technology. We may also need the cooperation of our collaborators to enforce or defend any intellectual property we contribute to or that arises out of our collaborations, which may not be provided to us.

We also anticipate that part of our strategy for pursuing the wide range of indications potentially addressed by ANKTIVA will involve further investigator-led clinical trials. While these trials generally provide us with valuable clinical data that can help form our future development strategy, we generally have less control over not only the conduct but also the design of these clinical trials. Third-party investigators may design clinical trials involving our product candidates with clinical endpoints that are more difficult to achieve or in other ways that increase the risk of negative clinical trial results compared to clinical trials we may design on our own. Negative results from investigator-led clinical trials, regardless of how the clinical trial was designed or conducted, could have a material adverse effect on our business and the perception of our product candidates.

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.

If third-party manufacturers, wholesalers, and distributors fail to perform as expected, or fail to devote sufficient time and resources to our approved product or other product candidates, our clinical development may be delayed, our costs may be higher than expected or our other product candidates may fail to be approved, or we may fail to commercialize our approved product or any other product candidates, if approved.

Our reliance on third-party manufacturers, wholesalers, and distributors exposes us to the following risks, any of which could delay FDA approval of our product candidates and commercialization of our approved product or any other product candidates, if approved, result in higher costs, or deprive us of potential product revenues:

- our CMOs, or other third parties we rely on, may encounter difficulties in achieving the volume of production needed to satisfy commercial demand, may experience technical issues that impact quality or compliance with applicable and strictly enforced regulations governing the manufacture of pharmaceutical products, and may experience shortages of qualified personnel to adequately staff production operations;

- our wholesalers and distributors could become unable to sell and deliver our approved product or other product candidates for regulatory, compliance, and other reasons;
- our CMOs, wholesalers, and distributors could breach or default on their agreements with us to meet our requirements for commercialization of our approved product or other product candidates;
- our CMOs, wholesalers, and distributors may not perform as agreed or may not remain in business for the time required to successfully produce, store, sell, and distribute our approved product or other product candidates and we may incur additional costs;
- our CMOs, wholesalers, and distributors may misappropriate our proprietary information; and
- if our CMOs, wholesalers, and distributors were to terminate our arrangements or fail to meet their contractual obligations, we may be forced to delay our commercial programs.

Our reliance on third parties reduces our control over our approved product and other product candidate development activities but does not relieve us of our responsibility to ensure compliance with all required legal, regulatory, and industry standards. For example, the FDA and other regulatory authorities require that our approved product, other product candidates and any other products that we may eventually commercialize be manufactured according to cGMP requirements. Any failure by our third-party manufacturers to comply with cGMP or maintain a compliance status acceptable to the FDA or other regulatory authorities or failure to scale up manufacturing processes, including any failure to deliver sufficient quantities of product candidates in a timely manner, could lead to a delay in, or failure to obtain, regulatory approval of any of our product candidates. On May 9, 2023, the FDA delivered a CRL to us regarding the BLA filed in May 2022, indicating that the FDA had determined that it could not approve the original BLA submission in its initial form, and the FDA made recommendations to address the issues raised. The deficiencies in the CRL related to the FDA's pre-license inspection of the company's third-party CMOs, among other items.

The CRL that we received in response to our initial BLA submission required us to resubmit the BLA to the FDA addressing the issues in the CRL. On April 22, 2024, the FDA approved ANKTIVA with BCG for the treatment of adult patients with BCG-unresponsive NMIBC with CIS with or without papillary tumors. Our third-party manufacturers are subject to periodic inspections by the FDA and other regulatory authorities, and failure to comply with cGMP could be the basis for the FDA to issue a warning or untitled letter, withdraw approvals for our approved product or our other product candidates previously granted to us, or take other regulatory or legal action, including a request to recall or seize our approved product or our other product candidates, total or partial suspension of production, suspension of clinical trials, refusal to approve pending applications or supplemental applications, detention of product, refusal to permit the import or export of other product candidates, injunction, imposing civil penalties or pursuing criminal prosecution.

Additionally, as we scale up manufacturing of our approved product or other product candidates and conduct required stability testing, we may encounter additional challenges or cGMP issues. These issues may require refinement or resolution in order to proceed with commercial marketing of our approved product or any of our other product candidates, if approved. In addition, quality issues may arise during scale-up and validation of commercial manufacturing processes. Any issues in our manufacturing process could result in increased scrutiny by regulatory authorities, delays in our regulatory review process, increases in our operating expenses, or failure to obtain or maintain approval for our approved product or other product candidates. If such issues relate to an approved product, we may not be able to commercialize the approved product as we planned or fail to meet commercial demand, any of which can materially and adversely affect our position in the market.

We use the Clinic, a related party, in some of our clinical trials which may expose us to significant regulatory risks. If our data for this site is not sufficiently robust or if there are any data integrity issues, we may be required to repeat such studies or contract with other clinical trial sites, which could delay and/or increase the cost of our development plans.

The Clinic has conducted, is currently conducting, and in the future may conduct clinical trials involving our product candidates. The Clinic is a related party as it is owned by an officer of the company and additionally, NantWorks manages the administrative operations of the Clinic. Prior to June 30, 2019, one of the company's officers was an investigator or sub-investigator for certain of the company's trials conducted at the Clinic. NantWorks, which is wholly owned by our Founder, Executive Chairman and Global Chief Scientific and Medical Officer, Dr. Soon-Shiong, provides certain administrative services (and has loaned money) to the Clinic. Under certain circumstances, we may be required to report some of these relationships to the FDA.

Relying on a related-party clinical site to develop data that is used as the basis to support regulatory approval can expose us to significant regulatory risks. The FDA may conclude that a financial relationship between us, the Clinic and/or a principal investigator has created a conflict of interest or otherwise affected interpretation of the study. The FDA or comparable regulatory authorities 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. If any data integrity, or regulatory non-compliance issues occur during the study, we may not be able to use the data for our regulatory approval. This could result in a delay in approval, or rejection, of our marketing applications by the FDA and may ultimately lead to the denial of regulatory approval of one or more of our product candidates.

We have formed, and may in the future form or seek, strategic alliances or enter into collaborations with third parties or additional licensing arrangements, and we may not realize the benefits of such alliances or licensing arrangements. Conflicts may arise between us and our collaborators or strategic partners, and such strategic alliances, collaborations or licensing arrangements may not be successful.

We have formed, and may in the future form or seek, strategic alliances, or enter into collaborations with third parties or additional licensing arrangements that we believe will complement or augment our development and commercialization efforts with respect to our approved product, other product candidates and any future product candidates that we may develop. We plan to collaborate with governmental, academic, and corporate partners, including affiliates, to improve and develop ANKTIVA and hAd5 constructs, and other cell therapies for new indications for use in combination with other therapies and to improve and develop other product candidates, which may expose us to additional risks, or we may not realize the benefits of such collaborations.

Because some of our collaborations are conducted at outside laboratories, and we do not have complete control over how the studies are conducted or reported, the results of such studies, which we may use as the basis for our conclusions, projections, or decisions with respect to our current or future product candidates, may be incorrect or unreliable, or may have a negative impact on us if the results of such studies are imputed to our product candidates or proposed indications, even if such imputation is improper. Additionally, we may use third-party data to analyze, reach conclusions or make predictions or decisions with respect to our product candidates that may be incomplete, inaccurate or otherwise unreliable.

We also plan to collaborate with governmental, academic and corporate partners, including affiliates, to improve and develop ANKTIVA and hAd5 constructs, cell therapies and other therapies for new indications for use in combination with other therapies and to improve and develop other product candidates, which may expose us to additional risks, or we may not realize the benefits of such collaborations.

Furthermore, conflicts may arise between us and our collaborators or strategic partners, and such strategic alliances, collaborations, or licensing arrangements may result in litigation, which is expensive and time consuming. For example, in 2019 Sorrento, with which we jointly established a new entity called NANTibody as a stand-alone biotechnology company, commenced litigation against us and certain of our officers and directors, alleging that we improperly caused NANTibody to acquire IgDraSol. Additionally, in 2020 we received a Request for Arbitration before the International Chamber of Commerce, International Court of Arbitration, served by Beike asserting a claim for breach of contract under our subsidiary Altor's license agreement with them. See Item 3. *"Legal Proceedings"* for more information regarding these disputes. Any such developments could harm our product development efforts, and additional disputes with our licensors or strategic collaborators may be expensive and time consuming.

In addition, collaborations involving our product candidates will be subject to numerous risks, which may include the following:

- collaborators, including their related or affiliated companies, may be entitled to receive exclusive rights for or involving our products;
- collaborators have significant discretion in determining the efforts and resources that they will apply to a collaboration;
- collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization of our product candidates based on clinical trial results, changes in their strategic focus due to the acquisition of competitive products, availability of funding or other external factors, such as a business combination that diverts resources or creates competing priorities;

- collaborators may delay clinical trials, provide insufficient funding for a clinical trial, stop a clinical trial, abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates;
- a collaborator with marketing and distribution rights to one or more products may not commit sufficient resources to their marketing and distribution;
- collaborators may not properly maintain, defend, or enforce our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes may arise between us and a collaborator that cause the delay or termination of the research, development, or commercialization of our product candidates, or that result in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates;
- if an agreement with any collaborator terminates, our access to technology and intellectual property licensed to us by that collaborator may be restricted or terminate entirely, which may delay our continued development of our product candidates using the collaborator's technology or intellectual property or require us to stop development of those product candidates completely; and
- collaborators may own or co-own intellectual property covering our product candidates or technology that results from our collaborating with them, and in such cases, we may not have the exclusive right to commercialize such intellectual property.

As a result, if we enter into collaboration agreements and strategic partnerships or license our product candidates, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture, which could delay our timelines or otherwise adversely affect our business. Additionally, exclusive rights that we may grant in connection with collaboration agreements may limit our ability to enter into new or additional collaboration agreements or strategic partnerships if we experience issues with existing collaborations. We also cannot be certain that, following a strategic transaction or license, we will achieve the revenues or specific net income that justifies such transaction. Any delays in entering into new collaborations or strategic partnership agreements related to our product candidates could delay the development and commercialization of our product candidates in certain geographies for certain indications, which would harm our business prospects, financial condition, and results of operations.

Any of these relationships may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing stockholders, or disrupt our management and business. In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view our product candidates as having the requisite potential to demonstrate safety and efficacy.

If conflicts arise between us and our collaborators or strategic partners, these parties may act in a manner adverse to us and could limit our ability to implement our strategies.

If conflicts arise between our corporate or academic collaborators or strategic partners and us, the other party may act in a manner adverse to us and could limit our ability to implement our strategies. Some of our existing academic collaborators and strategic partners are conducting multiple product development efforts. Such current or future collaborators or strategic partners could become our competitors in the future and could develop competing products, preclude us from entering into collaborations with their competitors, fail to obtain timely regulatory approvals, terminate their agreements with us prematurely or fail to devote sufficient resources to the commercialization of our approved product and the development and commercialization of our other product candidates. Competing product candidates, either developed by the collaborators or strategic partners or to which the collaborators or strategic partners have rights, may result in the withdrawal of our collaborator's or partner's support for our product or product candidates.

Our use of joint ventures, strategic partnerships, supply agreements, collaborations, and/or alliances may expose us to risks associated with jointly owned investments.

We may operate parts of our business through joint ventures, strategic partnerships, supply agreements, collaborations, and/or alliances with other companies. While such arrangements may, in some cases, give us access to technologies that we may not otherwise have or may give us access to capital, they involve risks not otherwise present in our own investments, including: (i) we may not control the venture, and it may divert management time and resources; (ii) the partner(s) may not agree to distributions that we believe are appropriate; (iii) we may experience impasses or disputes with such partner(s) on certain decisions, which could require us to expend additional resources to resolve such impasses or disputes, including litigation or arbitration; (iv) our partner(s) may become insolvent or bankrupt, fail to fund their share of required capital contributions or fail to fulfil their obligations as a venture partner; (v) the arrangements governing these relationships may contain certain conditions or milestone events that may never be satisfied or achieved; (vi) our partner(s) may have business or economic interests that are inconsistent with our interests and may take actions contrary to our interests; (vii) we may suffer losses as a result of actions taken by the partner(s); (viii) conflicts may arise leading to disputes and efforts to terminate these arrangements and seek other remedies; and (ix) it may be difficult for us to exit if an impasse arises or if we desire to sell our interest for any reason. For example, in December 2021 we established a joint venture with Amyris. However, in August 2023, Amyris announced that it had filed for Chapter 11 bankruptcy protection. As of December 31, 2024, the carrying amount of our equity investment in the joint venture was zero. There can be no guarantee that the strategic partnerships that we currently have or may enter into will be successful. Furthermore, we may, in certain circumstances, be liable for the actions of our partners. Any of the foregoing risks could have a material adverse effect on our business, financial condition and results of operations.

We are heavily dependent on our senior management, particularly Dr. Soon-Shiong, our Founder, Executive Chairman and Global Chief Scientific and Medical Officer, and a loss of a member of our senior management team in the future, even if only temporary, could harm our business.

Our operations will be dependent upon the services of our executives and our employees who are engaged in research and development. If we lose the services of members of our senior management, particularly Dr. Soon-Shiong, our Founder, Executive Chairman and Global Chief Scientific and Medical Officer, for a short or an extended time, for any reason, we may not be able to find appropriate replacements on a timely basis, and our business, financial condition and results of operations could be materially adversely affected. Our existing operations and our future development depend to a significant extent upon the performance and active participation of certain key individuals, particularly Dr. Soon-Shiong. Although Dr. Soon-Shiong focuses heavily on our matters and is highly active in our management, he devotes a significant amount of his time to a number of different endeavors and companies, including NantHealth, Inc., NantMedia Holdings, LLC (which operates the Los Angeles Times) and NantWorks, which is a collection of multiple companies in the healthcare and technology space. The risks related to our dependence upon Dr. Soon-Shiong are particularly acute given his ownership percentage, the commercial and other relationships that we have with entities affiliated with him, his role in our company and his public reputation. We may also be dependent on additional funding from Dr. Soon-Shiong and his affiliates, which may not be available when needed and which he is under no obligation to provide.

To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have provided, and plan to continue providing, equity incentive awards that vest over time. The value to employees of equity incentive awards that vest over time may be significantly affected by movements in our stock price that are beyond our control and may at any time be insufficient to counteract more lucrative offers from other companies. Despite our efforts to retain valuable employees, members of our management, scientific and development teams may terminate their employment with us on short notice. We do not have employment agreements with our NEOs and do not maintain “key man” insurance policies on the lives of most of the members of our management.

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

Our future financial performance and our ability to commercialize our approved product and other product candidates will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert a disproportionate amount of their attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities. In order to develop our business in accordance with our business plan, we will have to hire

additional qualified personnel, including in the areas of research, manufacturing, clinical trials management, regulatory affairs, and sales and marketing. We are continuing our efforts to recruit and hire the necessary employees to support our planned operations in the near term. However, competition for qualified personnel in the biotechnology and pharmaceuticals industry is intense due to the limited number of individuals who possess the skills and experience required, and no assurance can be given that we will be able attract, hire, retain and motivate the highly skilled employees that we need, on acceptable terms or at all. Future growth will impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining, and motivating additional employees;
- managing our internal development efforts effectively, including the clinical and FDA review process for our product candidates, while complying with our contractual obligations to contractors and other third parties; and
- improving our operational, financial and management controls, reporting systems, and procedures.

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

If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, we may not be able to successfully implement the tasks necessary to further commercialize our approved product or develop and commercialize our other product candidates and, accordingly, may not achieve our research, development, and commercialization goals on a timely basis, or at all.

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

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

- assimilation of operations, intellectual property, and products of an acquired company or product, including difficulties associated with integrating new personnel;
- the diversion of our management's attention from our existing product programs and initiatives in pursuing such a strategic merger or acquisition;
- retention of key employees, the loss of key personnel, and uncertainties in our ability to maintain key business relationships;
- significant upfront milestone and/or royalty payments from which we may not realize the anticipated benefits;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or product candidates and regulatory approvals; and
- our inability to generate revenues from acquired technology and/or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

Depending on the size and nature of future strategic acquisitions, we may acquire assets or businesses that require us to raise additional capital or to operate or manage businesses in which we have limited experience. Making larger acquisitions that require us to raise additional capital to fund the acquisition will expose us to the risks associated with capital raising activities. Acquiring and thereafter operating larger new businesses will also increase our management, operating and reporting costs and burdens (including increased cash requirements). In addition, if we undertake acquisitions, we may issue dilutive equity securities, assume or incur additional debt obligations or contingent liabilities, incur large one-time expenses and acquire intangible assets that could result in significant future amortization expense. Moreover, we may not be able to locate suitable acquisition opportunities, and this inability could impair our ability to grow or obtain access to technology or products that may be important to the development of our business.

A variety of risks associated with marketing our approved product and other product candidates internationally could materially adversely affect our business.

We plan to seek regulatory approval of our approved product and other product candidates outside of the U.S. and, accordingly, we expect that we will be subject to additional risks related to operating in foreign countries if we obtain the necessary approvals, including:

- differing regulatory requirements in foreign countries;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration, and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the U.S.;
- differing payor reimbursement regimes, governmental payors or patient self-pay systems, and price controls;
- potential liability under the FCPA or comparable foreign regulations;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the U.S.;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad;
- the impact of public health epidemics on the global economy, such as the coronavirus pandemic; and
- business interruptions resulting from geopolitical actions, including war and terrorism.

These and other risks associated with international operations may materially adversely affect our ability to attain or maintain profitable operations.

In particular, there is currently significant uncertainty about the future relationship between the U.S. and various other countries, most significantly China, as well as Mexico and Canada, with respect to trade policies, treaties, tariffs, taxes, and other limitations on cross-border operations. The U.S. government has made and continues to make significant additional changes in U.S. trade policy and may continue to take future actions that could negatively impact U.S. trade. For example, legislation has been introduced in Congress to limit certain U.S. biotechnology companies from using equipment or services produced or provided by select Chinese biotechnology companies, and others in Congress have advocated for the use of existing executive branch authorities to limit those Chinese service providers' ability to engage in business in the U.S. We cannot predict what actions may ultimately be taken with respect to trade relations between the U.S. and China or other countries, what products and services may be subject to such actions or what actions may be taken by the other countries in retaliation. If we are unable to obtain or use services from existing service providers or become unable to export or sell our products to any of our customers or service providers, our business, liquidity, financial condition, and/or results of operations would be materially and adversely affected.

We are party to a public-private partnership regarding our manufacturing facility in Dunkirk, New York, and our failure to meet the obligations of those agreements could materially impact our development, operations and prospects.

On February 14, 2022, we acquired a leasehold interest in the Dunkirk Facility from Athenex with a lease term that commenced on October 1, 2021 (the Commencement Date). To the extent we are able to address the construction needs and resolve the employment covenant-related matter with the lessor as described below, we believe this will provide us with a state-of-the-art biotech production center that will substantially expand and diversify our manufacturing capacity in the U.S. and the ability to scale production associated with certain of our product candidates.

We paid approximately $40.0 million to Athenex, and the leasehold interest in the Dunkirk Facility was transferred to us. Our annual lease payment will be $2.00 per year for an initial 10-year term, with an option to renew the lease under substantially the same terms and conditions for an additional 10-year term. As part of the transaction, we assumed obligations under various third-party agreements, and committed to spend $1.52 billion on operational expenses during the initial term, and an additional $1.50 billion on operational expenses if we elect to renew the lease for the additional 10-year term. We also committed to hiring 450 employees at the Dunkirk Facility within the first five years following the Commencement Date, with 300 such employees to be hired within the first 2.5 years following the Commencement Date. We are eligible for certain sales-tax exemption savings during the development of the Dunkirk Facility, and certain property tax savings over the next 20 years, subject to certain terms and conditions, including performance of certain of the obligations described above.

In addition, we believe that the Dunkirk Facility has construction needs that may require approximately 12 to 18 months to complete in order for it to be used as intended, and which needs remain as a result of an ongoing dispute with the Dunkirk Facility's general contractor and stay related to Athenex's ongoing bankruptcy proceedings, as described below. Consequently, during the third quarter of 2022, we determined to conduct a reduction-in-force of a significant portion of the then-current employees at the Dunkirk Facility, which became effective in late December 2022. The construction period and reduction-in-force have adversely affected our ability to satisfy certain operational obligations described above, including the initial employee count requirement, which was not timely satisfied and remains unsatisfied, and in addition, while we believe we have complied with all applicable federal and state laws implicated by the reduction-in-force, we could become subject to litigation in connection with these measures.

Failure to satisfy the obligations over the lease term, including the milestones we have committed to achieve, may give rise to certain rights and remedies of the lessor and other governmental authorities including, for example, termination of the lease agreement and other related agreements and potential recoupment of a percentage of the grant funding received by Athenex for construction of the Dunkirk Facility and other benefits received, subject to the terms and conditions of the applicable agreements. In November 2024, we received written notice from our landlord alleging non-compliance with the initial employee headcount requirement of our lease for the Dunkirk Facility. The landlord has agreed on a limited period of time to continue discussions regarding a potential resolution as well as a path forward to address the construction needs at the facility. If we are unable to remedy this alleged default or otherwise reach an acceptable resolution, the landlord may take action to terminate the lease and compel us to surrender the facility, among other remedies. While we are seeking to resolve this matter expeditiously, there can be no assurance that we will succeed in doing so. If we lose access to the Dunkirk Facility and related leased equipment, it could disrupt our operations and planned manufacturing activities, causing us to divert resources to find alternative facilities, which would not have any subsidies, and could have a significant impact on our operations and financial performance. We may also be subject to lawsuits or claims for damages against us if we are unable to comply with our obligations under these arrangements or in connection with other aspects of the Dunkirk Facility, which could materially and adversely affect our business, results of operations, and financial condition. In addition, we were named as a defendant in a lawsuit filed during the fourth quarter of 2022 by Exyte, the general contractor for the Dunkirk Facility, in New York state court arising from a construction agreement Exyte entered with Athenex pertaining to construction of the Dunkirk Facility. We believe we are entitled to defense costs and indemnification and, accordingly, we have provided notice to Athenex. On May 14, 2023, Athenex, together with certain of its subsidiaries, filed voluntary petitions for relief under Chapter 11 of the United States Bankruptcy Court for the Southern District of Texas. The lawsuit with Exyte has remained stayed as a result of Athenex's bankruptcy proceedings and the construction needs of the Dunkirk Facility remain. The extent of the impact of the Athenex Proceedings and its automatic stay will have on any continuing obligations Athenex may have under the purchase agreement remain unclear. We further believe Exyte's claims against us are without merit, and we intend to defend the claims vigorously. Further, the aforementioned litigation and bankruptcy have impacted our ability to address the construction needs at the Dunkirk Facility and may continue to have a negative impact on our efforts to operate the Dunkirk Facility.

Our counterparties in the public-private partnership for the Dunkirk Facility may fail to meet their obligations, which could materially impact our development, operations and prospects for the facility.

There is no guarantee that the counterparties to our public-private partnerships will comply with the terms of their agreements, including that their ability to fund their capital commitments under the agreements may be subject to their ability to raise additional capital and that further construction or operational timetables may not be met. Furthermore, while we believe that government funding will assist in funding a portion of the further buildout of the Dunkirk Facility, there can be no assurance as to the final acceptance and timing of the requests for government funding that we submit, and there may be disagreements in terms of the eligibility of reimbursement requests and related matters. Public-private partnerships are also subject to risks associated with government and government agency counterparties, including risks related to government relations compliance, sovereign immunity, shifts in the political environment, changing economic and legal conditions, and social dynamics.

Our contractors and subcontractors may place liens on our projects, and if they then successfully foreclose on such projects, we may not be able to use such assets for our business.

Under general property law, any contractor or subcontractor doing work on a project may attach a lien on the property with respect to which it does work to secure the dollar value of all labor and material furnished to the project. A valid lien holder could, after the lien is perfected, institute a collection suit, according to the lien, and if it were successful in obtaining a judgment, the real property and the equipment thereon could be foreclosed upon. If a contractor were to successfully foreclose on such liens, we may then not then be able to use such assets to manufacture our products, and our business could be materially harmed.

Risks Related to Healthcare and Other Government Regulations

While we have one FDA-approved product, we may be unable to obtain additional U.S. or foreign regulatory approval and, as a result, may be unable to commercialize our other product candidates. We are and will continue to be subject to ongoing extensive regulation, regulatory obligations and continued regulatory review, which may result in significant additional expense.

Our approved product and other product candidates are subject to extensive governmental regulations relating to, among other things, the research, development, testing, manufacture, quality control, import, export, safety, effectiveness, labeling, packaging, storage, distribution, record keeping, approval, advertising, promotion, marketing, post-approval monitoring and post-approval reporting of drugs and therapeutic biologics. Rigorous preclinical testing and clinical trials and an extensive regulatory review process are required to be successfully completed in the U.S. and in many foreign jurisdictions before a new drug or therapeutic biologic can be marketed. Satisfaction of these and other regulatory requirements is costly, lengthy, time-consuming, uncertain and subject to unanticipated delays and can vary substantially based upon the type, complexity and novelty of the products involved. We had previously received a CRL in response to our initial BLA submission, requiring us to resubmit the BLA to the FDA addressing the issues in the CRL. On April 22, 2024, the FDA approved ANKTIVA with BCG for the treatment of adult patients with BCG-unresponsive NMIBC with CIS with or without papillary tumors. We are required to comply with certain post-marketing commitments, including completion of our QUILT 3032 clinical trial and annual reporting for up to four years, with a final report submission to the FDA by the end of 2029.

During the fourth quarter of 2024, we submitted MAAs for ANKTIVA with BCG for the treatment of patients with BCG-Unresponsive NMIBC CIS to the EMA and the MHRA, which agencies accepted such MAAs for review in the first quarter of 2025. These are the first such submissions for us, the regulatory review process is uncertain, and there can be no assurance that the agencies will approve the MAAs on the anticipated timeline, or at all. Other than our approved product, we have not submitted any other marketing or drug approval applications to the FDA or comparable foreign authorities for any other product candidate, and we may never receive such regulatory approval for any of our other product candidates or regulatory approval that will allow us to successfully commercialize such other product candidates. In addition, regulatory agencies may lack experience with our technologies and products, which may lengthen the regulatory review process, increase our development costs and delay or prevent their commercialization.

Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical studies, clinical trials or other research. The number and types of preclinical studies and clinical trials that will be required for regulatory approval also vary depending on the product candidate, the disease or condition that the product candidate is designed to address and the regulations applicable to any particular product candidate. Approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our other product candidates.

Any delay in completing development or obtaining, or failing to obtain, required approvals would have a material and adverse effect on our ability to generate revenue from the particular product candidate for which we are developing and seeking approval. 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 may have obtained, be subject to other regulatory enforcement action, and we may not achieve or sustain profitability.

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

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

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

Failure to obtain regulatory approval in any targeted jurisdiction would prevent us from marketing our products to a larger patient population and reduce our commercial opportunities.

In order to market our products in the EU, UK, U.S. and other jurisdictions, we and any collaboration partners must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. The time required to obtain approval in other countries may differ from that required to obtain FDA approval. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval as well as additional or different risks, and we may not obtain foreign regulatory approvals on a timely basis, if at all. Approval by the European Commission, MHRA or the FDA does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or by the FDA. We or any collaboration partners may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our products in the EU, UK and other foreign jurisdictions or for new product candidates and/or new indications in the U.S. Failure to obtain these approvals would harm our business, financial condition and results of operations.

Even though we have received regulatory approval for our approved product, we will continue to be subject to ongoing regulatory requirements concerning it and our other product candidates, which may result in significant additional expenses. Additionally, our other product candidates, if approved, could be subject to labeling and other restrictions, and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our approved product or other product candidates.

Any regulatory approvals that we receive for our product candidates may also be subject to limitations on the approved indicated uses for which the product may be marketed, or to conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials, and surveillance to monitor safety and efficacy. In addition, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for any approved product, including our current product, will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, including reporting of certain adverse events as well as continued compliance with cGMP for the drug products, and GCP guidelines for any clinical trials that we conduct post-approval.

Later discovery of previously unknown problems with an approved product, including adverse events of unanticipated severity or frequency, or with manufacturing operations or processes, or failure to comply with regulatory requirements, may result in, among other things:

- holds on clinical trials;
- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market, or voluntary or mandatory product recalls;

- imposition of a REMS, which may include distribution or use restrictions;
- requirements to conduct additional post-market clinical trials to assess the safety of the product;
- revisions to the labeling, including limitation on approved uses or the addition of additional warnings, contraindications or other safety information, including boxed warnings;
- manufacturing delays and supply disruptions where regulatory inspections identify observations of non-compliance requiring remediation;
- fines, warning or untitled letters;
- refusal by the FDA to approve pending applications or supplements to approved applications submitted by us, or withdrawal of product approvals;
- product seizure or detention, or refusal to permit the import or export of product candidates; and
- injunctions or the imposition of civil or criminal penalties.

The FDA's policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the U.S. or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or are not able to maintain regulatory compliance, we 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 are unable to establish sales, marketing and distribution capabilities, we may not be successful in commercializing our approved product or our other product candidates if and when they are approved.

We are in the process of implementing our sales and marketing personnel hiring plan and building out key commercialization infrastructure for the commercialization of our approved product. To achieve commercial success for any other product for which we obtain marketing approval, we may need to hire additional sales and marketing personnel.

We have built, and are continuing to build, a focused sales and marketing infrastructure to market our approved product and potentially other product candidates in the U.S., if and when they are approved, including by partnering with experienced third party contractors. There are risks involved with establishing our own sales, marketing and distribution capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force is expensive and time-consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, including failure to receive marketing approval from the FDA, we would have prematurely or unnecessarily incurred these commercialization expenses. For example, we had previously hired sales and marketing personnel for a launch of our now-approved product, but we received a CRL from the FDA in May 2023. We may also inaccurately estimate the number of representatives needed to build our sales force, which may result in unnecessary expense or the inability to scale as quickly as needed. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel. Factors that may inhibit our efforts to commercialize our approved product and other product candidates, if approved, on our own include:

- our inability to recruit, train and retain adequate numbers of effective sales, marketing, reimbursement, customer service, medical affairs, and other support personnel;
- the inability of sales personnel to obtain access to physicians or increase market acceptance of our approved product or any other product candidate, if approved;
- the inability of reimbursement professionals to negotiate arrangements for coverage or adequate reimbursement by payors for our approved product or any other product candidate, if approved;
- the inability to price our approved product or any other product candidates, if approved, at a sufficient price point to ensure an adequate and attractive level of profitability;

- restricted or closed distribution channels that make it difficult to distribute our approved product or any other product candidates, if approved, to segments of the patient population; and
- unforeseen costs and expenses associated with creating an independent commercialization organization.

If we do not establish sales, marketing and distribution capabilities successfully, we will not be successful in commercializing our approved product or any other product candidates, if approved.

Problems related to large-scale commercial manufacturing could cause delays in product launches, an increase in product costs, product recalls or product shortages.

Manufacturing finished drug products, especially in large quantities, is complex. Our product, and if our other product candidates receive regulatory approval, will require several manufacturing steps and may involve complex techniques to ensure quality and sufficient quantity, especially as the manufacturing scale increases. Our approved product and other product candidates will need to be made consistently and in compliance with a clearly defined manufacturing process pursuant to FDA regulations. Accordingly, it will be essential to be able to validate and control the manufacturing process to ensure that it is reproducible. Slight deviations anywhere in the manufacturing process, including obtaining materials, filling, labeling, packaging, storage, shipping, quality control and testing, may result in lot failures, delay in the release of lots, product recalls or spoilage. Success rates can vary dramatically at different stages of the manufacturing process, which can lower yields and increase costs. We may experience deviations in the manufacturing process that may take significant time and resources to resolve and, if unresolved, may affect manufacturing output and cause us to fail to satisfy contractual commitments, cause recalls, lead to delays in our clinical trials or result in litigation or regulatory action. Such actions would hinder our ability to meet contractual obligations and could cause material adverse consequences for our business.

If we fail to comply with U.S. and foreign regulatory requirements, regulatory authorities could limit or withdraw any marketing or commercialization approvals we have or may receive and subject us to other penalties that could materially harm our business. For example, our GMP-in-a-Box may be regulated by the FDA as a medical device, and regulatory compliance for medical devices is expensive, complex and uncertain, and a failure to comply could lead to enforcement actions against us and other negative consequences for our business.

The FDA and similar agencies regulate medical devices. All of our potential medical device products and material modifications will be subject to extensive regulation and clearance or approval from the FDA and non-U.S. regulatory agencies prior to commercial sale and distribution as well as after clearance or approval. Complying with these regulations is costly, time-consuming, complex and uncertain. For instance, before a new medical device, or a new intended use for an existing device, can be marketed in the U.S., a company must first submit a premarket submission, such as a premarket notification (510(k)), *De Novo* request, or PMA, and receive clearance, *De Novo* grant, or approval from the FDA, unless an exemption applies.

Any regulatory approvals that we receive for our approved product and other product candidates will require surveillance to monitor the safety and efficacy of the product. The FDA and similar agencies have significant pre- and post-market authority, including requirements related to product design, development, testing, laboratory and preclinical studies, clinical trials approval, manufacturing processes and quality (including suppliers), labeling, packaging, distribution, adverse event and deviation reporting, storage, shipping, premarket clearance or approval, advertising, marketing, promotion, sale, import, export, product change, recalls, submissions of safety and effectiveness, post-market surveillance and reporting of deaths or serious injuries and certain malfunctions, and other post-marketing information and reports such as deviation reports, registration, product listing, annual user fees, and recordkeeping for our product candidates. The FDA may also require a REMS to approve our product candidates, which may impose further requirements or restrictions on the distribution or use of an approved drug or therapeutic biologic. The FDA may also require post-approval Phase 4 trials. Moreover, the FDA and comparable foreign regulatory authorities will continue to closely monitor the safety profile of any product even after approval.

Medical devices regulated by the FDA are subject to general controls which include: registration with the FDA; listing commercially distributed products with the FDA; complying with cGMP under QSR; filing reports with the FDA of and keeping records relative to certain types of adverse events associated with devices under the medical device reporting regulation; assuring that device labeling complies with device labeling requirements; and reporting certain device field removals and corrections to the FDA. In addition to the general controls, some Class 2 medical devices are also subject to special controls. Most medical devices

that require premarket review by the FDA, including most Class 2 medical devices, require the submission of a 510(k) or a *De Novo* request and obtaining 510(k) clearance or *De Novo* grant prior to marketing the device. Some devices known as 510(k)-exempt devices can be marketed without prior clearance or approval from the FDA. Most Class 3 devices are subject to the FDA's PMA requirement. Further, in February 2024, the FDA issued a final rule replacing the QSR with the QMSR, which incorporates by reference the quality management system requirements of ISO 13485:2016. The FDA has stated that the standards contained in ISO 13485:2016 are substantially similar to those set forth in the existing QSR. This final rule does not go into effect until February 2026.

The FDA can also refuse to clear or approve premarket submissions for any medical device we develop. We may not be able to obtain the necessary clearances or approvals or may be unduly delayed in doing so, for any medical device products we develop, which could harm our business. Furthermore, even if we are granted regulatory clearances or approvals for any medical device products, they may include significant limitations on the indicated uses for the product, which may limit the market for the product.

In addition, we, our contractors, and our collaborators are and will remain responsible for FDA compliance. We and any of our collaborators, including our CMOs, could be subject to periodic unannounced inspections by the FDA to monitor and ensure compliance with regulatory requirements. Application holders must further notify the FDA, and depending on the nature of the change, obtain FDA pre-approval for product and manufacturing changes. The cost of compliance with post-approval regulations may have a negative effect on our operating results and financial condition.

If the FDA or comparable foreign regulatory authorities become aware of new safety information or previously unknown problems after approval of our approved product or any of our other product candidates, including: (i) adverse events of unanticipated severity or frequency, (ii) that the product is less effective than previously thought, (iii) problems with our third-party manufacturers or manufacturing processes or (iv) failure to comply with regulatory requirements, or if we violate regulatory requirements at any stage, whether before or after marketing approval is obtained, we may face a number of regulatory consequences, including fines, warnings or untitled letters, holds on clinical trials, delay of approval or refusal by the FDA to approve pending applications or supplements to approved applications, suspension or withdrawal of regulatory approval, product recalls and seizures, administrative detention of products, refusal to permit the import or export of products, operating restrictions or partial suspension or total shutdown of production, injunctions, consent decrees, civil penalties and criminal prosecution, among other consequences. Additionally, we may face unanticipated expenditures to address or defend such actions and customer notifications for repair, replacement or refunds. Any such restrictions could limit sales of the product. Any of these events could further have other material and adverse effects on our operations and business and could adversely impact our stock price and could significantly harm our business, financial condition, results of operations, and prospects.

The FDA also regulates the advertising and promotion of medical devices to ensure that the claims are consistent with their regulatory clearances or approvals, that there are adequate and reasonable data to substantiate the claims and that the promotional labeling and advertising is neither false nor misleading in any respect. If the FDA determines that any of our advertising or promotional claims are misleading, not substantiated or not permissible, we may be subject to enforcement actions, including warning letters, and we may be required to revise our promotional claims and make other corrections or restitutions. Failure to comply with applicable U.S. requirements regarding, for example, promoting, manufacturing, or labeling our medical device products, may subject us to a variety of administrative or judicial actions and sanctions, such as Form 483 observations, warning letters, untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties and criminal prosecution. If any of our medical device products cause or contribute to a death or a serious injury or malfunction in certain ways, we will be required to report under applicable medical device reporting regulations, which can result in voluntary corrective actions or agency enforcement actions.

If any of these events were to occur, it would have a material and adverse effect on our business, financial condition and results of operations.

The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting pre-approval promotion and the promotion of off-label uses. If we or our sales and marketing partners violate these laws and regulations, we could face civil liability or encounter regulatory investigations and significant regulatory penalties and sanctions.

The FDA prohibits the pre-approval promotion of drugs as safe and effective for the purposes for which they are under investigation. Similarly, the FDA prohibits the promotion of approved drugs for new or unapproved indications. If the FDA finds that we have engaged in pre-approval promotion of our future product candidates, or if our approved product or any of our other product candidates are approved and we are found to have improperly promoted off-label uses of those products, we may become subject to significant liability. The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products, such as our approved product and other product candidates, if approved. In particular, an approved product may not be promoted for uses that are not approved by the FDA or such other regulatory agencies as reflected in the product's approved labeling. However, physicians may nevertheless prescribe our product, or any future approved product, to their patients in a manner that is inconsistent with the approved label, which is within their purview as part of their practice of medicine. If we are found to have promoted such off-label uses, however, 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. The FDA may also issue a public warning letter or untitled letter to the company. If we cannot successfully manage the promotion of our product or any future approved products, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

Inappropriate assumptions may be drawn based on results for patients who receive access to any of our non-approved product candidates through compassionate use, EAPs, or right to try access, which should not be viewed as representative of how the product candidate will perform in a well-controlled clinical trial.

We often receive requests for compassionate use access to our investigational drugs by patients that do not meet the entry criteria for enrollment into our clinical trials. Generally, patients requesting compassionate use have no other treatment alternatives for life-threatening conditions. We evaluate each compassionate use request on an individual basis, and in some cases grant access to our investigational product candidates outside of our sponsored clinical trials if a physician certifies that the patient receiving treatment is critically ill and does not meet the entry criteria for one of our open clinical trials. Individual patient results from compassionate use access may not be used to support submission of a regulatory application, may not support approval of a product candidate, and should not be considered to be indicative of results from any ongoing or future well-controlled clinical trial. Before we can seek regulatory approval for any of our product candidates, we must demonstrate in well-controlled clinical trials statistically significant evidence that the product candidate is both safe and effective for the indication for which we are seeking approval. The results of our compassionate use program may not be used to establish safety or efficacy or regulatory approval.

In addition, some patients who receive access to product candidates prior to their commercial approval through compassionate use, EAPs, or right to try access have life-threatening illnesses and have exhausted all other available therapies. The risk for SAEs in this patient population is high, which could have a negative impact on the safety profile of ANKTIVA or future product candidates, which could cause significant delays or an inability to successfully commercialize ANKTIVA or future product candidates, which could materially harm our business. We may in the future need to restructure or pause any future compassionate use and/or EAP we initiate in order to perform the controlled clinical trials required for regulatory approval and successful commercialization of ANKTIVA or future product candidates, which could prompt adverse publicity or other disruptions related to current or potential participants in such programs.

We are and will be 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 and/or civil liability and other serious consequences for violations, which can harm our business.

Our approved product and our other product candidates will be subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations and various economic and trade sanctions regulations administered by the OFAC, the FCPA, the U.S. domestic bribery statute contained in 18 U.S.C. §201, the U.S. Travel Act, the USA PATRIOT Act and possibly other state and national anti-bribery and anti-money laundering laws in countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, third-party intermediaries, joint venture partners and collaborators from authorizing, promising, offering or providing, directly or

indirectly, improper payments or benefits to recipients in the public or private sector. We use CROs abroad for clinical trials. In addition, we may engage third-party intermediaries to sell our approved product or other product candidates and solutions abroad once we enter a commercialization phase for our approved product or such other product candidates and/or to obtain necessary permits, licenses, and other regulatory approvals. We or our third-party intermediaries may have direct or indirect interactions with officials and employees of government agencies or state-owned or affiliated entities. We can be held liable for the corrupt or other illegal activities of these third-party intermediaries, our employees, representatives, contractors, partners and agents, even if we do not explicitly authorize or have actual knowledge of such activities. If we fail to comply with these laws and regulations, we and certain of our employees could be subject to substantial civil or 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.

We have adopted an anti-corruption policy, which mandates compliance with the FCPA and other anti-corruption laws applicable to our business throughout the world. However, there can be no assurance that our employees and third-party intermediaries will comply with this policy or such anti-corruption laws. Non-compliance with anti-corruption and anti-money laundering laws could subject us to whistleblower complaints, investigations, sanctions, settlements, prosecution, other investigations, or other enforcement actions. If such actions are launched, or governmental or other sanctions are imposed, or if we do not prevail in any possible civil or criminal litigation, our business, results of operations and financial condition could be materially harmed. In addition, responding to any action will likely result in a materially significant diversion of management's attention and resources and significant defense and compliance costs and other professional fees. In certain cases, enforcement authorities may even cause us to appoint an independent compliance monitor, which can result in added costs and administrative burdens.

There is currently significant uncertainty about the future relationship between the U.S. and various other countries, most significantly China, with respect to trade policies, treaties, tariffs, taxes, and other limitations on cross-border operations. The U.S. government has made and continues to make significant additional changes in U.S. trade policy and may continue to take future actions that could negatively impact U.S. trade. For example, legislation has been introduced in Congress to limit certain U.S. biotechnology companies from using equipment or services produced or provided by select Chinese biotechnology companies, and others in Congress have advocated for the use of existing executive branch authorities to limit those Chinese service providers' ability to engage in business in the U.S. We cannot predict what actions may ultimately be taken with respect to trade relations between the U.S. and China or other countries, what products and services may be subject to such actions or what actions may be taken by the other countries in retaliation. If we are unable to obtain or use services from existing service providers or become unable to export or sell our products to any of our customers, our business, liquidity, financial condition, and/or results of operations would be materially and adversely affected.

Our failure to comply with state, national and/or international privacy and security laws and regulations could lead to government enforcement actions and significant penalties against us and adversely impact our operating results.

There are numerous laws and regulations at the federal and state levels addressing privacy and security concerns, and some state laws apply more broadly than HIPAA and associated regulations. For example, the CCPA, which went into effect on January 1, 2020, provides, among other things, new privacy and security obligations for covered companies and new privacy rights to California consumers, including the right to opt out of certain sales of their personal information. The CCPA also provides for civil penalties as well as a private right of action with statutory damages for certain data breaches, thereby potentially increasing risks associated with a data breach. Although the CCPA includes limited exceptions, including for certain personal information collected as part of certain clinical trials or other biomedical research studies, it may regulate or impact our processing of personal information depending on the context. Additionally, the CPRA was approved by California voters in November 2020. The CPRA significantly modifies the CCPA, which may require us to modify our practices and policies and may further increase our compliance costs and potential liability. Certain states have also enacted or proposed privacy laws governing health information, including for example, Washington's My Health, My Data Act and Nevada's Senate Bill 370, and all 50 states have enacted laws imposing obligations to provide notification of certain security breaches of personal information. Additionally, several states have enacted or proposed laws similar to the CCPA, such as in New York, Virginia, Colorado, Utah, Connecticut, Iowa, Indiana, Montana, Tennessee, Oregon, Florida, Delaware, and Texas. These laws could mark the beginning of a further trend toward more stringent privacy laws in the U.S. and have prompted a number of proposals for new federal and state-level privacy laws. We cannot yet determine the impact these laws or changes may have on our business and operations but anticipate they could increase our compliance costs and potential liability, impair our ability to collect, use or otherwise process personal information, expose us to greater liability and require us to modify our practices and policies in an effort to comply.

There are also various laws and regulations in other jurisdictions relating to privacy and security. For example, EU member states and other foreign jurisdictions, including the UK and Switzerland, have adopted data protection laws and regulations which impose significant compliance obligations on us. The collection, use, and other processing of personal data, including patient or health data, in the EU, may be governed by the GDPR. The GDPR, which is wide-ranging in scope and applies extraterritorially, imposes, among other things, requirements relating to the consent of the individuals to whom the personal data relates, the notices provided to such individuals, the security and confidentiality of personal data, data breach notification, the adoption of appropriate privacy governance, including policies, procedures, training and audits, and the use of third-party processors in connection with the processing of personal data. The GDPR also imposes strict rules on the transfer of personal data out of the EU, including to the U.S., provides data protection authorities with enforcement authority and imposes large penalties for non-compliance, including the potential for fines of up to €20 million or up to 4% of the total worldwide annual global revenues of the noncompliant entity, whichever is greater. GDPR requirements apply not only to third-party personal data transfers, but also to transfers of personal data between us and our subsidiaries, including employee information. In addition, in January 2021, following its exit from the EU, the UK transposed the GDPR into its domestic law with its own version of the GDPR (combining the GDPR and the UK GDPR), which currently imposes the same obligations as the GDPR in most material respects and provides for fines of up £17.5 million or up to 4% of the total worldwide annual global revenues of the noncompliant entity, whichever is greater.

Complying with numerous, complex, and changing laws and regulations is expensive and difficult. Any actual or alleged failure to comply with any privacy or security law or regulation, or security breach or other incident, including those involving the misappropriation, loss, or other unauthorized use, disclosure or other processing of sensitive or confidential patient, consumer or other personal information, whether by us, one of our CROs or business associates or another third party, could adversely affect our business, financial condition, and results of operations, and could subject us to investigations, litigation, and other proceedings, material fines and penalties, compensatory, special, punitive and statutory damages, consent orders regarding our privacy and security practices, requirements that we provide notices, credit monitoring services and/or credit restoration services or other relevant services to impacted individuals, adverse actions against our licenses to do business, reputational damage, and injunctive relief. The enactment of, and changes to, privacy and security laws and regulations have increased our responsibility and potential liability, including in relation to the personal data that we process and our clinical trials, and we may be required to put in place additional mechanisms in an effort to comply with applicable laws and regulations, which could divert management's attention and increase our cost of doing business. In addition, any new law or regulation relating to privacy and security, or any applicable industry standard, may increase our costs of doing business. In this regard, we expect that there will continue to be new proposed laws, regulations and industry standards relating to privacy and security in the U.S., the UK, the EU, and other jurisdictions, and we cannot determine the impact such future laws, regulations and standards may have on our business.

We cannot assure you that our CROs or other third-party service providers with access to our or our customers', suppliers', trial patients' and employees' personal information or other sensitive or confidential information will not breach applicable laws or regulations or contractual obligations imposed by us, or that they will not experience security breaches or incidents, which could have a corresponding effect on our business, including putting us in breach of our obligations under privacy and security laws and regulations and/or which could in turn adversely affect our business, results of operations and financial condition. We cannot assure you that the measures and safeguards we have taken will protect us from the foregoing risks, any of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

We and our third-party contractors must comply with environmental, health and safety laws and regulations. A failure to comply with these laws and regulations could expose us to significant costs or liabilities.

We and any of our third-party CMOs or suppliers are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, generation, manufacture, storage, treatment and disposal of hazardous materials and wastes. Hazardous chemicals, including flammable and biological materials, are involved in certain aspects of our business, and we cannot eliminate the risk of injury or contamination from the use, generation, manufacture, distribution, storage, handling, treatment or disposal of hazardous materials and wastes. In the event of contamination or injury, or failure to comply with such environmental, health and safety laws and regulations, we could be held liable for any resulting damages, fines and penalties associated with such liability, which could exceed our assets and resources.

Although we will maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of biological or hazardous materials or wastes arising out of and in the course of employment, this insurance may not provide adequate coverage against potential liabilities. We do not maintain comprehensive insurance coverage for liabilities arising from medical or hazardous materials, environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological or hazardous materials.

Environmental, health and safety laws and regulations are becoming increasingly more stringent. We may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts, which could harm our business, prospects, financial condition or results of operations. Our failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Coverage and reimbursement may be limited or unavailable in certain market segments for our approved product or other product candidates, which could make it difficult for us to sell our approved product or other product candidates profitably.

In both domestic and foreign markets, sales of our approved product or other product candidates, if approved, depend on the availability of coverage and adequate reimbursement from third-party payors. Third-party payors, whether domestic or foreign, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. Regulatory authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications, which could affect our ability or that of our collaborators to sell our product candidates profitably. In addition, third-party payors are requiring higher levels of evidence of the benefits and clinical outcomes of new technologies and are challenging the prices charged. Patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Patients are unlikely to use our approved product or other product candidates unless coverage is provided, and reimbursement is adequate to cover a significant portion of the cost of our approved product or other product candidates. Such third-party payors include government health programs such as Medicare and Medicaid, managed care providers, private health insurers and other organizations. Obtaining coverage and adequate reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance. In addition, because our approved product and other product candidates represent new approaches to the treatment of cancer, we cannot accurately estimate the potential revenues from our approved product or other product candidates.

Government authorities and third-party payors decide which drugs and treatments they will cover and the amount of reimbursement. Coverage decisions may depend upon clinical and economic standards that disfavor new drug products when more established or lower cost therapeutic alternatives are already available or subsequently become available. These payors may not view our approved product or other future products, if any, as cost-effective, and coverage and reimbursement may not be available to our customers, or those of our collaborators, or may not be sufficient to allow our approved product or other future approved products, if any, to be marketed on a competitive basis. If reimbursement is not available, or is available only to limited levels, our product and other product candidates may be competitively disadvantaged, and we, or our collaborators, may not be able to successfully commercialize our approved product or other product candidates. Alternatively, securing favorable reimbursement terms may require us to compromise pricing and prevent us from realizing an adequate margin over cost. Reimbursement by a third-party payor may depend upon a number of factors, including, but not limited to, the third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

In the U.S., no uniform policy of coverage and reimbursement for products exists among third-party payors. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our approved product and our other product candidates, if approved, to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained. Moreover, the factors noted above have continued to be the focus of policy and regulatory debate that has, thus far, shown the potential for movement towards permanent policy changes; this trend is likely to continue, and may result in more or less favorable impacts on pricing. The recent and ongoing series of congressional hearings relating to drug pricing has presented heightened attention to the biopharmaceutical industry, creating the potential for political and public pressure, while the potential for resulting legislative or policy changes presents uncertainty. Congress has considered and may continue to consider legislation that, if passed, could have significant impact on prices of prescription drugs covered by

Medicare, including limitations on drug price increases. The impact of these regulations and any future healthcare measures and agency rules on us and the pharmaceutical industry as a whole is currently unknown. Further, changes in the leadership of the FDA and other federal agencies may lead to new policies, changes in regulations, or disruptions to the operations of the federal agencies, any of which may impact our clinical development plans. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our approved product and other product candidates if approved. Complying with any new legislation and regulatory changes could be time-intensive and expensive, resulting in a material adverse effect on our business.

Prices paid for a drug also vary depending on the class of trade. Prices charged to government customers are subject to price controls, including ceilings, and private institutions obtain discounts through group purchasing organizations. Net prices for drugs may be further reduced by mandatory discounts or rebates required by government healthcare programs and demanded by private payors. It is also not uncommon for market conditions to warrant multiple discounts to different customers on the same unit, such as purchase discounts to institutional care providers and rebates to the health plans that pay them, which reduces the net realization on the original sale.

In addition, federal programs impose penalties on manufacturers of drugs marketed under a BLA or NDA, in the form of mandatory additional rebates and/or discounts if commercial prices increase at a rate greater than the Consumer Price Index-Urban, and these rebates and/or discounts, which can be substantial, may impact our ability to raise commercial prices. For example, under the American Rescue Plan Act of 2021, the statutory cap on Medicaid Drug Rebate Program rebates that manufacturers pay to state Medicaid programs has been eliminated. Elimination of this cap may require pharmaceutical manufacturers to pay more in rebates than they receive on the sale of products, which could have a material impact on our business. In August 2022, Congress passed the IRA, which includes prescription drug provisions that have significant implications for the pharmaceutical industry and Medicare beneficiaries, including allowing the federal government to negotiate a maximum fair price for certain high-priced single source Medicare drugs, imposing penalties and excise tax for manufacturers that fail to comply with the drug price negotiation requirements, requiring inflation rebates for all Medicare Part B and Part D drugs, with limited exceptions, if their drug prices increase faster than inflation, and redesigning Medicare Part D to reduce out-of-pocket prescription drug costs for beneficiaries, among other changes. Only high-expenditure single-source drugs that have been approved for at least 7 years (11 years for single-source biologics) can qualify for negotiation, with the negotiated price taking effect 2 years after the selection year. For 2026, the first year in which negotiated prices become effective, CMS selected 10 high-cost Medicare Part D drugs in 2023, negotiations began in 2024, and the negotiated maximum fair price for each drug has been announced. CMS has selected 15 additional Medicare Part D drugs for negotiated maximum fair pricing in 2027. For 2028, up to an additional 15 drugs, which may be covered under either Medicare Part B or Part D, will be selected, and for 2029 and subsequent years, up to 20 additional Medicare Part B or Part D drugs will be selected. Various industry stakeholders, including certain pharmaceutical companies and the Pharmaceutical Research and Manufacturers of America, have initiated lawsuits against the federal government asserting that the price negotiation provisions of the IRA are unconstitutional. The impact of these judicial challenges, legislative, executive, and administrative actions and any future healthcare measures and agency rules on us and the pharmaceutical industry as a whole is unclear. Cost control initiatives could cause us, or our collaborators, to decrease, discount, or rebate a portion of the price we, or they, might establish for products, which could result in lower than anticipated product revenues. If the prices realized for our approved product or other product candidates, if any, decrease or if governmental and other third-party payors do not provide adequate coverage or reimbursement, our prospects for revenues and profitability will suffer.

Even if we obtain coverage for a given product, the resulting approved reimbursement payment rates might not be high enough to allow us to establish or maintain a market share sufficient to realize a sufficient return on our or their investments or achieve or sustain profitability or may require co-payments that patients find unacceptably high. If payors subject our approved product or other product candidates to maximum payment amounts or impose limitations that make it difficult to obtain reimbursement, providers may choose to use therapies which are less expensive when compared to our approved product or other product candidates. Additionally, if payors require high co-payments, beneficiaries may decline our therapies and seek alternative therapies and physicians may be reluctant to recommend our approved product to their patients. We may need to conduct post-marketing studies in order to demonstrate the cost-effectiveness of any future products to the satisfaction of physicians and other target customers and third-party payors. Such studies might require us to commit a significant amount of management time and financial and other resources. Our future products might not ultimately be considered cost-effective. Adequate third-party coverage and reimbursement might not be available to enable us to maintain price levels sufficient to realize an appropriate return on investment in product development.

We, and our collaborators, cannot be sure that coverage will be available for our approved product or any other product candidate that we, or they, commercialize and, if available, that the reimbursement rates will be adequate. Further, the net reimbursement for drug products may be subject to additional reductions if there are changes to laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the U.S. An inability to promptly obtain coverage and adequate payment rates from both government-funded and private payors for any of our product candidates for which we obtain marketing approval could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products, and our overall financial condition.

There have been, and likely will continue to be, legislative and regulatory proposals at the federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future. 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 approved product or other product candidates if we obtain regulatory approval;
- our ability to set a price that we believe is fair for our approved product and other product candidates;
- our ability to generate revenues and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors, which may adversely affect our future profitability. A possible challenge for our approved product and other product candidates arises from the fact that they may potentially be used in an inpatient setting. Inpatient reimbursement generally relies on stringent packaging rules that may mean that there is no separate payment for our approved product or other product candidates. Additionally, data used to set the payment rates for inpatient admissions is usually several years old and would not take into account all of the additional therapy costs associated with the administration of our other product candidates. If special rules are not created for reimbursement for immunotherapy treatments such as our approved product or other product candidates, hospitals might not receive enough reimbursement to cover their costs of treatment, which will have a negative effect on their adoption of our approved product or other product candidates.

Further, the codes used by providers to bill for our approved product could also affect reimbursement. J-codes are codes maintained by the CMS, which are a component of the HCPCS and are typically used to report injectable drugs that ordinarily cannot be self-administered. In October 2024, we were assigned a J-code for ANKTIVA, which will be valid for use beginning on January 1, 2025. To date, we do not have a specific J-code for any of our other product candidates. We cannot guarantee that a J-code will be granted for any of our other product candidates, if approved. To the extent separate coverage or reimbursement is available for our approved candidate or any other product candidates, if approved, and a specific J-code is not available, physicians would need to use a non-specific miscellaneous J-code to bill third-party payors for these physician-administered drugs. Because miscellaneous J-codes may be used for a wide variety of products, health plans may have more difficulty determining the actual product used and billed for the patient. These claims must often be submitted with additional information and manually processed, which can create delays in claims processing times as well as increasing the likelihood for claim denials and claim errors. As a result, until our J-code for ANKTIVA can be used in 2025, we may experience slower than expected commercial sales.

We may face difficulties from changes to current regulations and future legislation.

In the U.S. and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our approved product or other product candidates, restrict or regulate post-approval activities, and affect our ability, or the ability of our collaborators, to profitably sell any products for which we obtain marketing approval. We expect that current laws, as well as other federal and state healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria, increased regulatory burdens and operating costs, decreased revenues from our biopharmaceutical product candidates, decreased potential returns from our development efforts, and additional downward pressure on the price that we, or our collaborators, may receive for any approved products.

Since enactment of the ACA in 2010, in both the U.S. and certain foreign jurisdictions, there have been a number of legislative and regulatory changes to the health care system that could impact our ability to sell our approved product or other product candidates profitably. These changes included aggregate reductions of Medicare payments to providers of up to 2% per fiscal year, effective April 1, 2013, which, due to subsequent legislative amendments, will stay in effect through 2032, with the exception of a temporary suspension implemented under various COVID-19 relief legislation. In January 2013, the ATRA was approved which, among other things, reduced Medicare payments to several providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on customers for our approved product or other product candidates, if approved, and accordingly, our financial operations.

Since its enactment, various portions of the ACA have been subject to judicial and constitutional challenges. In June 2021, the United States Supreme Court held that Texas and other challengers had no legal standing to challenge the ACA, dismissing the case without specifically ruling on the constitutionality of the ACA. Accordingly, the ACA remains in effect in its current form. It is unclear how future litigation or healthcare measures will impact our business, financial condition and results of operations. Complying with any new legislation or reversing changes implemented under the ACA could be time-intensive and expensive, resulting in a material adverse effect on our business.

Any reduction in reimbursement from Medicare or other government healthcare programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenues, attain profitability or commercialize our approved product or other product candidates.

Legislative and regulatory proposals may also be made to expand post-approval requirements and restrict sales and promotional activities for drugs. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance, or interpretations will be changed, or what the impact of such changes on the marketing approvals of our approved product or other product candidates, if any, may be. In addition, increased scrutiny by Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements. Recently, the Supreme Court overruled the *Chevron* doctrine, which gives deference to regulatory agencies' statutory interpretations in litigation against federal government agencies, such as the FDA, where the law is ambiguous. This landmark Supreme Court decision may invite more companies and other stakeholders to bring lawsuits against the FDA to challenge longstanding decisions and policies of the FDA, including the FDA's statutory interpretations of market exclusivities and the "substantial evidence" requirements for drug approvals, which could undermine the FDA's authority, lead to uncertainties in the industry, and disrupt the FDA's normal operations, any of which could delay the FDA's review of our regulatory submissions. We cannot predict the full impact of this decision, future judicial challenges brought against the FDA, or the nature or extent of government regulation that may arise from future legislation or administrative action.

In addition, there have been increasing legislative efforts and enforcement interest in the U.S. with respect to drug pricing practices, including Congressional inquiries and proposed federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. As discussed above, in August 2022, Congress passed the IRA, which includes prescription drug provisions that have significant implications for the pharmaceutical industry and Medicare beneficiaries, including allowing the federal government to negotiate a maximum fair price for certain high-priced single source Medicare drugs, imposing penalties and excise tax for manufacturers that fail to comply with the drug price negotiation requirements, requiring inflation rebates for all Medicare Part B and Part D drugs, with limited exceptions, if their drug prices increase faster than inflation, and redesigning Medicare Part D to reduce out-of-pocket prescription drug costs for beneficiaries, among other changes. Various stakeholders have initiated lawsuits against the federal government asserting that the price negotiation provisions of the IRA are unconstitutional. The impact of these judicial challenges, future litigation in view of the Supreme Court's overturn of the *Chevron* decision, legislative, executive, and administrative actions and any future healthcare measures and agency rules implemented by the government on us and the pharmaceutical industry as a whole is unclear. 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 and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. For example, the FDA recently authorized the state of Florida to import certain prescription drugs from Canada for a period of two years to help reduce drug costs, provided that Florida's Agency for Health Care Administration meets the requirements set forth by the FDA. Other states may follow Florida.

We are unable to predict the future course of federal or state healthcare legislation in the U.S. directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. The ACA and any further changes in the law or regulatory framework that reduce our revenues or increase our costs could also have a material and adverse effect on our business, financial condition and results of operations. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our current product candidates and any future product candidates or additional pricing pressures.

Governments outside the U.S. tend to impose strict price controls, which may adversely affect our revenues, if any.

In international markets, reimbursement and health care payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. In some countries, particularly the countries of the EU, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain coverage and reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. There can be no assurance that our product candidates will be considered cost-effective by third-party payors, that an adequate level of reimbursement will be available, or that the third-party payors' reimbursement policies will not adversely affect our ability to sell our product candidates profitably. If reimbursement of our product or other product candidates is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed, possibly materially.

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

We are exposed to the risk of employee fraud or other illegal activity by our employees, independent contractors, consultants, commercial partners, principal investigators, CROs, CMO's, suppliers and vendors. Misconduct by these parties could include intentional, reckless and/or negligent conduct that fails to: comply with the laws of the FDA and other similar foreign regulatory bodies, provide true, complete and accurate information to the FDA and other similar foreign regulatory bodies, comply with manufacturing standards we have established, comply with healthcare fraud and abuse laws in the U.S. and similar foreign fraudulent misconduct laws, or report financial information or data accurately or to disclose unauthorized activities to us. As we begin commercializing our approved product and may in the future commercialize our other product candidates, if any, in the U.S., our potential exposure under such laws will increase significantly, and our costs associated with compliance with such laws are also likely to increase. In particular, the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws and regulations designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commission(s), certain customer incentive programs and other business arrangements. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials, which could result in regulatory sanctions and serious harm to our reputation.

It is not always possible to identify and deter misconduct or other improper activities by our employees or third parties that we engage for our business operations and the precautions we take to detect and prevent inappropriate conduct 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 comply with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a material adverse effect on our business, financial condition, results of operations and prospects, including the imposition of significant fines or other sanctions, including exclusion from government healthcare programs, and serious harm to our reputation. In addition, the approval and commercialization of any of our product candidates outside the U.S. will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws. Efforts to ensure that our business arrangements will comply with applicable healthcare laws may involve substantial costs.

Our relationships with health care professionals, institutional providers, principal investigators, consultants, potential customers and third-party payors are, and will continue to be, subject, directly and indirectly, to federal and state health care fraud and abuse, false claims, marketing expenditure tracking and disclosure, government price reporting, and privacy and security laws. If we are unable to comply, or have not fully complied, with such laws, we could face significant penalties and liabilities.

Our business operations and activities may be directly or indirectly subject to various federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute and the federal FCA. As we begin commercializing our approved product and may in the future commercialize our other product candidates, if any, in the U.S., our potential exposure under such laws will increase significantly, and our costs associated with compliance with such laws are also likely to increase.

Our current and future arrangements with healthcare professionals, clinical investigators, CROs, third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our products for which we obtain marketing approval. In addition, we may be subject to laws of the federal government and state governments in which we conduct our business relating to privacy and security with respect to patient or health data. The laws that may affect our ability to operate include, but are not limited to:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual for a healthcare item or service, or the purchasing or ordering of an item or service, for which payment may be made under a federal healthcare program such as Medicare or Medicaid;
- the U.S. federal false claims and civil monetary penalties laws, including the federal civil FCA, which prohibit, among other things, individuals or entities from knowingly presenting or causing to be presented, claims for payment by government funded programs such as Medicare or Medicaid that are false or fraudulent, and which may apply to us by virtue of statements and representations made to customers or third parties;
- HIPAA, which created additional federal criminal statutes that prohibit, among other things, knowingly and willfully executing or attempting to execute a scheme to defraud healthcare programs, as well as;
- HIPAA, as amended by HITECH, which imposes requirements on certain types of people and entities relating to the privacy, security, and transmission of PHI, and requires notification to affected individuals and regulatory authorities of certain breaches of the privacy or security of PHI, and other U.S. laws and foreign laws that govern the privacy or security of health or patient data;
- the federal Physician Payment Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, to report annually to the CMS information related to payments and other transfers of value to covered recipients, including physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare providers (such as physician assistants and nurse practitioners) and teaching hospitals, and ownership and investment interests held by physicians and their immediate family members, which is published in a searchable form on an annual basis;
- federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making, or causing to be made, false statements relating to healthcare matters;
- the federal Civil Monetary Penalties Law, which prohibits, among other things, offering or transferring remuneration to a federal healthcare beneficiary that a person knows or should know is likely to influence the beneficiary's decision to order or receive items or services reimbursable by the government from a particular provider or supplier;
- the FCPA, the U.K. Bribery Act of 2010, and other local anti-corruption laws that apply to our international activities; and
- state laws comparable to each of the above federal laws, such as, for example, anti-kickback and false claims laws that may be broader in scope and also apply to commercial insurers and other non-federal payors, requirements for mandatory corporate regulatory compliance programs, and laws relating to patient or health data, privacy or security. Other state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, and require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures.

We expect to incur increased costs of compliance with such laws and regulations as they continue to evolve. If we or our contractors are unable to comply, or have not fully complied, with such laws, we could face penalties, including, without limitation, civil, criminal, and administrative penalties, damages, monetary fines, disgorgement, possible exclusion from participation in Medicare, Medicaid and other federal and state health care programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment or restructuring of our operations. Any of these could adversely affect our business, financial condition, and results of operations.

As we grow our business and expand our sales organization or rely on distributors outside of the U.S., we would be at increased risk of violating these laws or our internal policies and procedures. The risk of us being found in violation of these or other laws and regulations is further increased by the fact that many have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Any action brought against us for violation of these or other laws or regulations, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business.

Disruptions at the FDA, the SEC and other government agencies caused by funding shortages could hinder their ability to hire and retain key leadership and other personnel, prevent new products from being developed or commercialized in a timely manner, or otherwise prevent those agencies from performing normal business functions, which could negatively impact our business and the approval of our future BLA submissions, as well as adversely affect the U.S. and global economy and our liquidity, financial condition and earnings.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels and related government shutdowns, the ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely is subject to the impacts of political events, which are inherently fluid and unpredictable. Changes in the leadership of the FDA and other federal agencies may also lead to new policies and changes in the regulations and operations of the FDA, including measures implemented by the Department of Government Efficiency, any of which may impact our clinical development plans.

Disruptions at the FDA and other agencies, including disruptions due to public health concerns, resurgence of COVID-19 cases, travel restrictions, or staffing shortages, may slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which could adversely affect our business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. If a prolonged government shutdown occurs in the future, including as a result of any failure by the U.S. federal government to increase the debt ceiling, it could significantly impact the ability of the FDA and the SEC to timely review and process our submissions, as well as cause interest rates and borrowing costs to further increase, which may negatively impact our ability to access the debt markets, including the corporate bond markets, on favorable terms, which could have a material adverse effect on our business, financial condition and results of operations and/or our BLA submissions.

Risks Related to Intellectual Property

If we are unable to obtain, maintain, protect and enforce patent protection and other proprietary rights for our approved product and other product candidates and technologies, we may not be able to compete effectively or operate profitably and may lose our ability to prevent our competitors from commercializing similar or identical technology and our approved product and other product candidates would be adversely affected.

Our success is dependent in large part on our obtaining, maintaining, protecting and enforcing patents and other proprietary rights in the U.S. and other countries with respect to our approved product and other product candidates and technology and on our ability to avoid infringing the intellectual property and other proprietary rights of others. Certain of our intellectual property rights are licensed from other entities, and as such the preparation and prosecution of any such patents and patent applications was not performed by us or under our control. Furthermore, patent law relating to the scope of claims in the biotechnology field in which we operate is still evolving and, consequently, patent positions in our industry may not be as strong as in other more well-established fields. The patent positions of biotechnology and pharmaceutical companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved and have been the subject of much litigation in recent years. No consistent policy regarding the breadth of claims allowed in biotechnology patents has emerged to date. As a result, the issuance, scope, validity, enforceability, or commercial value of our patent rights remain highly uncertain.

Any future patents we obtain may not be sufficiently broad to prevent others from using our technology or from developing competing therapeutics and technology. There is no guarantee that any of our pending patent applications will result in issued or granted patents, any of our issued or granted patents will not later be found to be invalid or unenforceable, or any issued or granted patents will include claims sufficiently broad to cover our product candidates and technology, or to provide meaningful protection from our competitors. Our owned or in-licensed pending and future patent applications may not result in patents being issued that protect our ANKTIVA and hAd5 constructs, cell-based therapies or other product candidates and technologies that effectively prevent others from commercializing competitive technologies and product candidates.

Moreover, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if patent applications we license or own currently or in the future issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. Any patents that we own or in-license may be challenged, narrowed, circumvented, or invalidated by third parties. Consequently, we do not know whether our ANKTIVA and hAd5 constructs, cell-based therapies or other product candidates and technologies will be protectable or remain protected by valid and enforceable patents. Our competitors or other third parties may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner which could materially adversely affect our business, financial condition, results of operations and growth prospects.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability and it is uncertain how much protection, if any, will be provided by our patents, including if they are challenged in the courts or patent offices or in other proceedings, such as re-examinations or oppositions, which may be brought in the U.S. or foreign jurisdictions to challenge the validity of a patent. A third party may challenge the validity or enforceability of a patent after its issuance. It is possible that a competitor may successfully challenge our patents or that a challenge will result in limiting their coverage. Moreover, it is possible that competitors may infringe our patents or successfully avoid the patented technology through design innovation. To counter infringement or other unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming, even if we were successful in stopping the violation of our patent rights.

We or our licensors may be subject to a third-party preissuance submission of prior art to the USPTO, or become involved in opposition, derivation, revocation, reexamination, post-grant and *inter partes* review, or interference proceedings or other similar proceedings challenging our owned or licensed patent rights. Should third parties file patent applications, or be issued patents claiming technology also used or claimed by our licensor(s) or by us in any future patent application, we, or one of our licensors, may be required to participate in interference proceedings in the USPTO to determine priority of invention for those patents or patent applications that are subject to the first-to-invent law in the U.S., or may be required to participate in derivation proceedings in the USPTO for those patents or patent applications that are subject to the first-inventor-to-file law in the U.S. We may be required to participate in such interference or derivation proceedings involving our issued patents and pending applications. We may also be required to participate in post-grant challenge proceedings, such as oppositions in a foreign patent office, which challenge our or our licensor's priority of invention or other features of patentability with respect to our owned or in-licensed patents and patent applications. Such challenges may result in loss of patent rights, loss of exclusivity, or in patent claims being narrowed, invalidated, or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of patent protection of our ANKTIVA and hAd5 constructs, cell-based therapies or other product candidates and technologies. An adverse determination in any of the type of submissions described above, proceeding or litigation could reduce the scope of, or invalidate or render unenforceable, our owned or in-licensed patent rights, allow third parties to commercialize our ANKTIVA and hAd5 constructs, cell-based therapies or other product candidates or technologies and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights.

If we or our collaborators are unsuccessful in any such proceeding or other priority or inventorship dispute, we may be required to cease using the technology or to obtain and maintain license rights from prevailing third parties, including parties involved in any such interference proceedings or other priority or inventorship disputes. A prevailing party in that case may not offer us a license on commercially acceptable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments. If we are unable to obtain and maintain such licenses, we may need to cease the development, manufacture, and commercialization of one or more of the product candidates we may develop. The loss of exclusivity or the narrowing of our owned and licensed patent claims could limit our ability to stop others from using or commercializing similar or identical technology and products. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

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

Some of our owned and in-licensed patents and patent applications are, and may in the future be, co-owned with third parties. In addition, certain of our licensors co-own the patents and patent applications we in-license with other third parties with whom we do not have a direct relationship. Our exclusive rights to certain of these patents and patent applications are dependent, in part, on inter-institutional or other operating agreements between the joint owners of such patents and patent applications, who are not parties to our license agreements. If our licensors do not have exclusive control of the grant of licenses under any such third-party co-owners' interest in such patents or patent applications or we are otherwise unable to secure such exclusive rights, 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 growth prospects.

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

Changes in either the patent laws or their interpretation in the U.S. and other countries may diminish our ability to protect our inventions, obtain, maintain, and enforce our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our owned and licensed patents. With respect to both in-licensed and owned intellectual property, we cannot predict whether the patent applications we and our licensors are currently pursuing will be issued as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient protection from competitors or other third parties. The patent prosecution process is expensive, time-consuming, and complex, and we may not be able to file, prosecute, maintain, enforce, or license all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output in time to obtain patent protection. Although we enter into nondisclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, CROs, CMOs, consultants, advisors, and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. In addition, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our inventions and the prior art allow our inventions to be patentable over the prior art. Furthermore, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the U.S. and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain whether we or our licensors were the first to make the inventions claimed in any of our owned or licensed patents or pending patent applications, or that we or our licensors were the first to file for patent protection of such inventions.

We or our licensors, collaborators, 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 intellectual property or the patents or other intellectual property of our licensors, all of which could be expensive, time-consuming and unsuccessful, may delay or prevent the development and commercialization of our product candidates, or may put our patents and other proprietary rights at risk.

If we or one of our licensors initiate legal proceedings against a third party to enforce a patent covering one of our product candidates or other technologies, the defendant could counterclaim that the patent is invalid and/or unenforceable or that we infringe their patents. In patent litigation in the U.S., defendant counterclaims alleging invalidity and/or unenforceability are commonplace, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or other applicable body, or made a misleading statement, during prosecution. Third parties may also raise similar claims before administrative bodies in the U.S. or abroad, even outside the context of litigation. Such mechanisms include re-examination, post grant review, *inter partes* review, interference proceedings, derivation proceedings, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings).

With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we, our licensor, our or our licensor's patent counsel and the patent examiner were unaware during prosecution. Moreover, even if our patents were to survive such a litigation challenge to their validity, the patents might still be held to be valid but unenforceable if a court were to decide that the patents are being enforced in a manner inconsistent with the antitrust laws, or that the patents were obtained through deceit during patent office examination or other such failure of sufficient candor to the patent office. If a third party were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our product candidates. Such a loss of patent protection could have a material adverse impact on our business, financial condition, results of operations and prospects.

The cost to us of any litigation or other proceeding relating to intellectual property rights, even if resolved in our favor, could be substantial. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources, including our scientists and management, from our business.

An adverse result in any litigation or defense proceeding could put one or more of our owned or licensed patents at risk of being invalidated, held unenforceable, or interpreted narrowly, and could put our patent applications at risk of not being issued. Such proceedings could result in revocation or cancellation of, or amendment to, our patents in such a way that they no longer cover our product candidates or technologies. If the outcome of litigation is adverse to us, third parties may be able to use our patented invention without payment to us. In addition, in an infringement proceeding, there is a risk that a court may decide that one or more of our patents is not valid or is unenforceable and that we do not have the right to stop the other party from using the inventions. There is also the risk that, even if the validity of our patents were upheld, a court would refuse to stop the other party on the grounds that its activities are not covered by, that is, do not infringe, our patents. 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 conduct such litigation or proceedings adequately. Some of our competitors may be better 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. The outcome following legal assertions of invalidity and unenforceability is unpredictable. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

The use of our technology and product or our other product candidates could potentially conflict with the rights of others, and third-party claims of intellectual property infringement, misappropriation or other violation against us, our licensors or our collaborators may prevent or delay the development and commercialization of our product, product candidates and technologies.

Our commercial success depends in part on our, our licensors' and our collaborators' ability to avoid infringing, misappropriating and otherwise violating the patents and other intellectual property rights of third parties. There is a substantial amount of complex litigation involving patents and other intellectual property rights in the biopharmaceutical industry. Our potential competitors or other parties may have, develop or acquire patent or other intellectual property rights that they could assert against us. If they do so, then we may be required to alter our approved product or other product candidates, pay licensing fees or cease our development and commercialization activities with respect to the applicable approved product or product candidates or technologies. If our approved product or other product candidates conflict with patent or other intellectual property rights of others, such parties could bring legal actions against us or our collaborators, licensees, suppliers or customers, claiming damages and seeking to enjoin manufacturing, use and marketing of the affected products.

Although we have conducted FTO analyses of the patent landscape with respect to our approved product or other product candidates and continue to undertake FTO analyses of our manufacturing processes, no FTO analysis can be considered exhausted because patent applications do not publish for 18 months, and the claims of patent applications can change over time. We may not be aware of patents that have already been issued and that a competitor or other third party might assert are infringed by our approved product or other product candidates or technologies. It is also possible that we could be found to have infringed patents owned by third parties of which we are aware, but which we do not believe are relevant to our approved product or other product candidates or technologies. In addition, because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that our approved product or other product candidates or technologies may infringe. Furthermore, patent and other intellectual property rights in biotechnology remains an evolving area with many risks and uncertainties. As such, we may not be able to ensure that we can market our approved product or other product candidates without conflict with the rights of others.

If intellectual property-related legal actions asserted against us are successful, in addition to any potential liability for damages (including treble damages and attorneys' fees for willful infringement), we could be enjoined from, or required to obtain a license to continue, manufacturing, promoting the use of or marketing the affected products. We may not prevail in any legal action and a required license under the applicable patent or other intellectual property may not be available on acceptable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments. We also could be required to redesign our infringing products, which may be impossible or require substantial time and monetary expenditure.

Defense of infringement claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of management and other employee resources from our business, and may impact our reputation. Some of our competitors may be able to sustain the costs of litigation or administrative proceedings more effectively than we can because of greater financial resources. 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. The occurrence of any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our approved product and other product candidates.

As is the case with other immunotherapy and biopharmaceutical companies, our success is dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity, and is therefore costly, time-consuming and inherently uncertain. In addition, the U.S. has recently enacted and is currently implementing wide-ranging patent reform legislation. Assuming that other requirements for patentability are met, prior to March 2013, in the U.S., the first to invent the claimed invention was entitled to the patent, while outside the U.S., the first to file a patent application was entitled to the patent. After March 2013, under the America Invents Act enacted in September 2011, the U.S. transitioned to a first-to-file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. A third party that files a patent application in the USPTO after March 2013, but before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before such third party made it. This will require us to be cognizant of the time from invention to filing of a patent application. Since patent applications in the U.S. and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we or our licensors were the first to either file any patent application related to our product candidates or other technologies or invent any of the inventions claimed in our or our licensor's patents or patent applications. The America Invents Act also includes a number of significant changes that affect the way patent applications will be prosecuted and also may affect patent litigation. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO-administered post-grant proceedings, including post-grant review, inter partes review, and derivation proceedings. Therefore, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our owned or in-licensed patent applications and the enforcement or defense of our owned or in-licensed issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Additionally, United States Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened 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 Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. For example, the United States Supreme Court held in *Amgen v. Sanofi (2023* that a functionally claimed genus was invalid for failing to comply with the enablement requirement of the Patent Act. While we do not believe that any of the patents owned or licensed by us will be found invalid based on the foregoing, we cannot predict how future decisions by Congress, the federal courts or the USPTO may impact the value of our patents.

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

Periodic maintenance fees, renewal fees, annuity fees, and various other government fees on patents and patent applications are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of a patent. The USPTO and various foreign governmental patent agencies require compliance with several procedural, documentary, fee payment and other similar provisions during the patent application process. In certain circumstances, we rely on our licensors to pay these fees and take the necessary actions to comply with these requirements. 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, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In such an event, our competitors might be able to enter the market with similar or identical products or technology, which would have a material adverse impact on our business, financial condition, results of operations and prospects.

Our rights to develop and commercialize our product candidates and technologies are subject, in part, to the terms and conditions of licenses granted to us by others.

License agreements may not provide exclusive rights to use certain licensed intellectual property and technology in all relevant fields of use and in all territories in which we may wish to commercialize our technology and product candidates in the future. As a result, we may not be able to prevent competitors or other third parties from developing and commercializing competitive products that also utilize technology that we have in-licensed.

In addition, subject to the terms of any such license agreements, we do not have the right to control the preparation, filing, prosecution and maintenance, and we may not have the right to control the enforcement, and defense of patents and patent applications covering the technology that we license from third parties. We cannot be certain that our in-licensed or out-licensed patents and patent applications that are controlled by our licensors or licensees will be prepared, filed, prosecuted, maintained, enforced, and defended in a manner consistent with the best interests of our business. If our licensors or licensees fail to prosecute, maintain, enforce, and defend such patents, or lose rights to those patents or patent applications, the rights we have licensed may be reduced or eliminated, our right to develop and commercialize our approved product and any of our product candidates that are subject of such licensed rights could be adversely affected, and we may not be able to prevent competitors from making, using and selling competing products. In addition, even where we have the right to control patent prosecution of patents and patent applications we have licensed to and from third parties, we may still be adversely affected or prejudiced by actions or inactions of our licensees, our licensors and their counsel that took place prior to the date upon which we assumed control over patent prosecution.

Furthermore, our owned and in-licensed patents may be subject to a reservation of rights by one or more third parties. For example, certain of our in-licensed intellectual property was funded in part by the U.S. government. As a result, the U.S. government may have certain rights to such intellectual property. When new technologies are developed with U.S. government funding, the U.S. government generally obtains certain rights in any resulting patents, including a non-exclusive license authorizing the U.S. government to use the invention or to have others use the invention on its behalf. The U.S. government's rights may also permit it to disclose the funded inventions and technology to third parties and to exercise

march-in rights to use or allow third parties to use the technology we have licensed that was developed using U.S. government funding. The U.S. government may exercise its march-in rights if it determines that action is necessary because we fail to achieve practical application of the government-funded technology, or because action is necessary to alleviate health or safety needs, to meet requirements of federal regulations, or to give preference to U.S. industry. In addition, our rights in such inventions may be subject to certain requirements to manufacture products embodying such inventions in the U.S. in certain circumstances if this requirement is not waived. Any exercise by the U.S. government of such rights or by any third party of its reserved rights could have a material adverse effect on our competitive position, business, financial condition, results of operations and growth prospects.

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

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

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

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

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

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

We have limited foreign intellectual property rights and may not be able to protect our intellectual property rights in various jurisdictions throughout the world.

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

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

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

Geo-political 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 the Russia-Ukraine war 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. If such an event were to occur, it could have a material adverse effect on our business. In addition, a decree was adopted by the Russian government in March 2022 allowing Russian companies and individuals to exploit inventions owned by patentees that have citizenship or nationality in, are registered in, or have a predominately primary place of business or profit-making activities in the U.S. and other countries that Russia has deemed unfriendly 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.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed trade secrets or other confidential information of third parties or claims asserting ownership of what we regard as our own intellectual property.

We have received confidential and proprietary information from third parties and their employees and contractors. In addition, we plan to employ and contract with individuals who were previously employed at other biotechnology or pharmaceutical companies. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed the trade secrets or other confidential information of these third parties or our employees' former employers. Litigation may be necessary to defend against or pursue these claims. Even if we are successful in resolving these claims, litigation could result in substantial cost and be a distraction to our management and employees.

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

We may not be able to license or acquire new or necessary intellectual property rights or technology from third parties.

An element of our intellectual property strategy is to license intellectual property rights and technologies from third parties and/or our affiliates. Other parties, including our competitors or our affiliates, may have patents relevant to our business, may have already filed patent applications relevant to our business, and are likely filing patent applications potentially relevant to our business. In order to avoid infringing these patents, we may find it necessary or prudent to obtain licenses to such patents from such parties. In addition, with respect to any patents we co-own with other parties, including our affiliates, we may require licenses to such co-owners' interest to such patents. The licensing or acquisition of intellectual property rights is a competitive area, and other more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources, and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. No assurance can be given that we will be successful in licensing any additional rights or technologies from third parties and/or our affiliates. Our inability to license the rights and technologies that we have identified, or that we may in the future identify, could have a material adverse impact on our ability to complete the development of our product candidates or to develop additional product candidates. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments. Failure to obtain any necessary rights or licenses may detrimentally affect our planned development of our current or future additional product candidates and could increase the cost, and extend the timelines associated with our development, of such other products, and we may have to abandon development of the relevant program or product candidate. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

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

Depending upon the timing, duration and specifics of any FDA marketing approval of any product candidates we may develop, including our approved product, one or more of our owned or in-licensed U.S. patents may be eligible for limited patent term extension under the Hatch-Waxman Act. The Hatch-Waxman Act permits a patent term extension of up to five years as compensation for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval. Only one patent may be extended per new drug, and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. Similar extensions as compensation for patent term lost during regulatory review processes are also available in certain foreign countries and territories, such as in Europe under a Supplementary Patent Certificate. However, we may not be granted an extension in the U.S. and/or foreign countries and territories because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of

relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is shorter than what we request, our competitors may obtain approval of competing products following our patent expiration, and our business, financial condition, results of operations and growth prospects could be materially harmed.

We may be subject to claims challenging rights in our patents and other intellectual property.

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

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

In addition to seeking patents for ANKTIVA, hAd5 technologies and constructs, cell therapies, and other product candidates and technologies, we also rely on trade secrets and confidentiality agreements to protect our unpatented know-how, technology, and other proprietary information and to maintain our competitive position. Trade secrets and know-how can be difficult to protect. We expect our trade secrets and know-how will over time be disseminated within the industry through independent development, the publication of journal articles describing the methodology, and the movement of personnel from academic to industry scientific positions.

We seek to protect these trade secrets and other proprietary technology, in part, by entering into nondisclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, CROs, CMOs, consultants, advisors, and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants as well as train our employees not to bring or use proprietary information or technology from former employers to us or in their work and remind former employees when they leave their employment of their confidentiality obligations. We cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary technology and processes. Despite our efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive, and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the U.S. are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor or other third party, our competitive position would be materially and adversely harmed.

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 registered or unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively, and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our business, financial condition, results of operations and growth prospects.

Intellectual property rights do not necessarily address all potential threats.

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

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

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

Risks Related to Our Common Stock

Dr. Soon-Shiong, our Founder, Executive Chairman, Global Chief Scientific and Medical Officer and principal stockholder, has significant interests in other companies which may conflict with our interests.

Our Founder, Executive Chairman and Global Chief Scientific and Medical Officer, Dr. Soon-Shiong, is also the founder of NantWorks. The various NantWorks companies are currently exploring opportunities in the immunotherapy, oncology, infectious disease, and inflammatory disease fields. In particular, we have agreements with a number of related parties that provide services, technology and equipment for use in their efforts to develop their product pipelines. Dr. Soon-Shiong holds a controlling interest, either directly or indirectly, in these entities. Consequently, Dr. Soon-Shiong's interests may not be aligned with our other stockholders, and he may from time to time be incentivized to take certain actions that benefit his other interests and that our other stockholders do not view as being in their interest as investors in our company. In addition, other companies affiliated with Dr. Soon-Shiong may compete with us for business opportunities or, in the future, develop products that are competitive with ours (including products in other therapeutic fields which we may target in the future). Moreover, even if they do not directly relate to us, actions taken by Dr. Soon-Shiong and the companies with which he is involved could impact us.

We are also pursuing supply arrangements for various investigational agents controlled by affiliates to be used in their clinical trials. If Dr. Soon-Shiong were to cease his affiliation with us or NantWorks, these entities may be unwilling to continue these relationships with us on commercially reasonable terms, or at all, and as a result may impede our ability to control the supply chain for our combination therapies. These collaboration agreements do not typically specify how sales will be apportioned between the parties upon successful commercialization of the product. As a result, we cannot guarantee that we will receive a percentage of the revenue that is at least proportional to the cost that we will incur in commercializing the product candidate.

We have entered into shared services agreements with NantWorks, pursuant to which the respective parties and their affiliates provide corporate, general and administrative and other support services to each other. If Dr. Soon-Shiong was to cease his affiliation with us or with NantWorks, we may be unable to establish or maintain this relationship with NantWorks on a commercially reasonable basis, if at all. As a result, we could experience a lack of business continuity due to loss of historical and institutional knowledge and new employees and/or new service providers lack of familiarity of with business processes, operating requirements, policies and procedures, and we may incur additional costs as new employees and/or service providers gain necessary experience. In addition, the loss of the services of NantWorks might significantly delay or prevent the commercialization of our approved product or the development of our other product candidates or achievement of other business objectives by diverting management's attention to transition matters and identification of suitable replacements, if any, and could have a material adverse effect on our business and results of operations.

Dr. Soon-Shiong, through his voting control of the company, has the ability to control actions that require stockholder approval.

Dr. Soon-Shiong, through his direct and indirect ownership of the company's common stock, has voting control of the company. As of December 31, 2024, Dr. Soon-Shiong and his affiliates owned approximately 76.2% of our common stock outstanding. Dr. Soon-Shiong and his affiliates also own our outstanding convertible promissory note, certain warrants and stock options to purchase shares of our common stock, and certain CVRs as described under "—Conversion of related-party promissory note, exercise of outstanding warrants and options to purchase our common stock, the achievement of the milestone under our outstanding CVRs, and potential additional equity issuances may dilute the ownership interest of existing stockholders or may otherwise depress the price of our common stock" below.

Dr. Soon-Shiong is in a position to control the outcome of corporate actions that require, or may be accomplished by, stockholder approval, including amending the bylaws of the company, the election or removal of directors and transactions involving a change of control. Dr. Soon-Shiong's controlling ownership could limit the ability of the remaining stockholders of the company to influence corporate matters, and the interests of Dr. Soon-Shiong may not coincide with the company's interests or the interests of its remaining stockholders.

In addition, pursuant to the Nominating Agreement between us and Cambridge, an entity that Dr. Soon-Shiong controls, Cambridge has the ability to designate one director to be nominated for election to the Board of Directors for as long as Cambridge continues to hold at least 20% of the issued and outstanding shares of our common stock. Dr. Soon-Shiong was selected by Cambridge to hold this board seat. Dr. Soon-Shiong and his affiliates will therefore have significant influence over management and significant control over matters requiring stockholder approval, including the annual election of directors and significant corporate transactions, such as a merger or other sale of our company or its assets, for the foreseeable future. This control will limit stockholders' ability to influence corporate matters and, as a result, we may take actions that our stockholders do not view as beneficial. As a result, the market price of our common stock could be adversely affected.

Conversion of our related-party promissory note, exercise of outstanding warrants and options to purchase our common stock, the achievement of the milestone under our outstanding CVRs, and potential additional equity issuances may dilute the ownership interest of existing stockholders or may otherwise depress the price of our common stock.

As of December 31, 2024, our indebtedness was comprised of a $505.0 million convertible promissory note held by an entity affiliated with Dr. Soon-Shiong that is convertible into shares of our common stock under certain circumstances. The note bears interest at Term SOFR plus 8.0% per annum, which provides that the noteholder has the sole option to convert all (but not less than all) of the outstanding principal amount and accrued but unpaid interest into shares of the company's common stock at a conversion price of $5.4270 per share (subject to appropriate adjustment from time to time for any stock dividend, stock split, combination of shares, reorganization, recapitalization, reclassification or other similar event).

In addition, as of December 31, 2024, we had outstanding warrants, stock options and unvested RSU awards covering the issuance of up to:

- 6,399,171 shares of our common stock at an exercise price of $3.2946 per share, which are currently exercisable with an expiration date of July 24, 2026 (these warrants were issued to certain institutional investors);
- any shares of our common stock that may be issued upon the exercise of the $5.0 million option held by Oberland, for which the price per share shall be determined by the 30-day trailing volume weighted-average price of our common stock, calculated from the date of exercise, and which option is exercisable by Oberland until the earliest of (i) December 29, 2028, (ii) a change of control of the company, or (iii) a sale of substantially all of the company's assets;

- 3,162,648 stock options and RSU awards issued to Dr. Soon-Shiong that are outstanding as of December 31, 2024, of which 1,392,730 are vested and exercisable and 1,769,918 are unvested and unexercisable; and
- 1,638,000 shares of our common stock at an exercise price of $3.24 per share exercisable from the 30th day following the achievement of a performance-based vesting condition pertaining to building manufacturing capacity to support supply requirements for ANKTIVA (which has not yet been satisfied) with an expiration date on the tenth anniversary of such initial exercise date (this warrant was issued to an affiliate of Dr. Soon-Shiong).

In addition, as of December 31, 2024, we had approximately $300.6 million CVRs outstanding that were issued to the former stockholders of Altor, including Dr. Soon-Shiong and certain affiliates, which such stockholders may choose to receive either in cash or shares of our common stock based upon an average of closing prices on a 20-trading day trailing period, upon the first calendar year prior to December 31, 2026 in which worldwide net sales of ANKTIVA exceed $1.0 billion. ANKTIVA with BCG for the treatment of adult patients with BCG-unresponsive NMIBC with CIS with or without papillary tumors was approved for commercial sale in April 2024, but there can be no assurance that such sales milestone will be achieved. Dr. Soon-Shiong and his related party hold approximately $139.8 million of such CVRs, and have irrevocably agreed to receive shares of the company's common stock in satisfaction of their CVRs.

The conversion or exchange of some or all of our outstanding promissory note into shares of our common stock, the exercise of any of our outstanding warrants and stock options, and the decision of the holders of our CVRs to receive shares of our common stock could dilute the ownership interests of existing stockholders. Any sales in the public market of our outstanding promissory note or warrants, or our common stock issuable upon conversion of our promissory note or exercise of the warrants or options, could adversely affect prevailing market prices of our common stock.

The market price of our common stock has been and may continue to be volatile, and investors may have difficulty selling their shares.

Although our common stock is listed on the Nasdaq Global Select Market, the market for our shares has demonstrated varying levels of trading activity. You may not be able to sell your shares quickly or at the market price if trading in shares of our common stock is not active. Further, 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 partnerships or acquire companies or products by using our shares of common stock as consideration.

The stock market in general and the market for biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. The market price of our common stock has been and may continue to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control, including:

- the commencement, enrollment or results of the planned clinical trials of our non-FDA-approved product candidates or any future clinical trials we may conduct, or changes in the development status of such product candidates;
- any delay in our regulatory submissions for our product candidates and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such submissions, including without limitation the FDA's issuance of a CRL or a "refusal to file" letter or a request for additional information;
- adverse results or delays in clinical trials;
- our decision to initiate a clinical trial, not to initiate a clinical trial or to terminate an existing clinical trial;
- adverse regulatory decisions, including failure to receive regulatory approval of our product candidates;
- changes in laws or regulations applicable to our approved product or other product candidates, including but not limited to clinical trial requirements for approvals;
- our failure to commercialize our approved product or other product candidates;
- additions or departures of key scientific or management personnel;
- unanticipated serious safety concerns related to the use of our approved product or other product candidates;
- announcements by us or our competitors of significant contracts, acquisitions, strategic partnerships, joint ventures or capital commitments;

- our ability to effectively manage our growth;
- variations in our quarterly operating results, including those driven by liability accounting associated with embedded derivatives;
- our liquidity position, RIPA liability covenants and the amount and nature of any debt we may incur;
- announcements that our revenue or income are below or that costs or losses are greater than analysts' expectations;
- publication of research reports about us or our industry, or immunotherapy in particular, or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- changes in the market valuations of similar companies;
- sales of large blocks of our common stock;
- fluctuations in stock market prices and volumes;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- significant lawsuits, including patent or stockholder litigation;
- the perception of our clinical trial results by retail investors, which investors may be subject to the influence of information provided by third party investor websites and independent authors distributing information on the internet;
- general economic slowdowns;
- government-imposed lockdowns, supply chain disruptions, and adverse economic effects from a potential pandemic, epidemic, or outbreak of an infectious disease, in the U.S. and abroad;
- geopolitical tensions and war, including the war in Ukraine and ongoing conflicts in Gaza and Yemen;
- coordinated actions by independent third-party actors to affect the price of certain stocks, coordinated via the internet and otherwise; and
- other factors described in this "*Risk Factors*" section.

In the past, securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company's securities. This type of litigation could result in substantial costs and a diversion of management's attention and resources, which would harm our business, operating results, or financial condition.

We are currently subject to securities class action litigation and other litigation and may be subject to similar or other litigation in the future, all of which will require significant management time and attention, result in significant legal expenses and may result in unfavorable outcomes, which may have a material adverse effect on our business, operating results and financial condition, and negatively affect the price of our common stock.

We are, and may in the future become, subject to various legal proceedings and claims that arise in or outside the ordinary course of business. The results of the securities class action lawsuit, the derivative action and any future legal proceedings cannot be predicted with certainty. Also, our insurance coverage may be insufficient, our assets may be insufficient to cover any amounts that exceed our insurance coverage, and we may have to pay damage awards or otherwise may enter into a settlement arrangement in connection with such claim. Any such payments or settlement arrangements in current or future litigation could have a material adverse effect on our business, operating results, or financial condition. Even if the plaintiffs' claims are not successful, current or future litigation could result in substantial costs and significantly and adversely impact our reputation and divert management's attention and resources, which could have a material adverse effect on our business, operating results and financial condition, and negatively affect the price of our common stock. In addition, such lawsuits may make it more difficult to finance our operations.

For example, on June 30, 2023, a putative securities class action complaint, captioned *Salzman v. ImmunityBio, Inc. et al.*, No. 3:23-cv-01216-BEN-WVG, was filed in the United States District Court for the Southern District of California against the company and three of its officers and/or directors, asserting violations of Sections 10(b) and 20(a) of the Exchange Act stemming from the company's disclosure on May 11, 2023 that it had received an FDA CRL stating, among other things, that it could not approve the company's original BLA submission in its initial form due to deficiencies related to its pre-license inspection of the company's third-party CMOs. On October 29, 2024, a shareholder derivative action was filed in the District Court for the Southern District of California against the members of our Board of Directors and certain officers, captioned *Van Luven v. Soon-Shiong et al.,* Case No. 3:24-cv-02014-L-AHG, on February 25, 2025, a second shareholder derivative action was filed in the United States District Court for the Southern District of California against certain members of our Board of Directors and certain officers, captioned *Barbieri v. Soon-Shiong, et al.*, Case No. 3:25-cv-00416-AGS-JB, and on February 26, 2025, a third shareholder derivative action was filed in the United States District Court for the Southern District of California against certain current and former members of our Board of Directors and certain officers, captioned *Shin v. Soon-Shiong, et al*., Case No. 3:25-cv-00423-JAH-DDL. Stemming from the same May 11, 2023 disclosure, these derivative complaints allege that the individual defendants breached their fiduciary duties by authorizing or permitting materially false and misleading statements and/or omitting material adverse facts regarding ImmunityBio's third-party CMOs and the prospects for regulatory approval of the ANKTIVA BLA. See Item 3. *"Legal Proceedings"* for more information.

Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plan, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. If our stockholders sell, or the market perceives that our stockholders intend to sell substantial amounts of our common stock in the public market, including shares obtained from the conversion or exchange of our convertible promissory note, exercise of our warrants, satisfaction of our CVRs, or the exercise or settlement of our equity incentive awards, the market price of our common stock could decline significantly. In addition, our Founder, Executive Chairman and Global Chief Scientific and Medical Officer, Dr. Soon-Shiong, and his affiliates owned approximately 76.2% of our common stock outstanding as of December 31, 2024. Sales of stock by Dr. Soon-Shiong and his affiliates could have an adverse effect on the trading price of our common stock.

Certain holders of our common stock are entitled to certain rights with respect to the registration of their shares under the Securities Act, including the shares purchased by affiliates of Oberland in connection with our entry into the RIPA. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares held by our affiliates as defined in Rule 144 under the Securities Act. Any sales of securities by these stockholders could have an adverse effect on the market price of our common stock.

In addition, we expect that additional capital may be needed in the future to continue our planned operations, including conducting clinical trials, regulatory approval efforts, pre-commercialization and commercialization activities, expanded research and development activities, and costs associated with operating as a public company. To raise capital, we may sell common stock, convertible securities, or other equity securities (including warrants) in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities, or other equity securities, existing investors may be materially diluted, and new investors could gain rights, preferences, and privileges senior to the holders of our common stock. The issuance of additional shares of common stock or warrants to purchase common stock, perception that such issuances may occur, or the exercise of outstanding warrants or other equity securities will have a material dilutive impact on existing stockholders and could have a material negative effect on the market price of our common stock.

We have incurred and will continue to incur costs as a result of operating as a public company and our management has been and will be required to devote substantial time to compliance initiatives and corporate governance practices, including maintaining an effective system of internal control over financial reporting.

As a public company listed in the U.S., we have incurred and will continue to incur significant additional legal, accounting, and other expenses as a result of operating as a public company. In addition, changing laws, regulations and standards relating to corporate governance and public disclosure, including Sarbanes-Oxley and regulations implemented by the SEC and Nasdaq, may increase legal and financial compliance costs and make some activities more time consuming. These laws, regulations and standards are subject to varying interpretations and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. We intend to invest resources to create a larger finance function with additional personnel to comply with evolving laws, regulations and standards, and this investment will result in increased

general and administrative expenses and a diversion of management's time and attention from revenue-generating activities to compliance activities. If, notwithstanding our efforts to comply with new laws, regulations and standards, we fail to comply, regulatory authorities may initiate legal proceedings against us, and our business may be harmed. As of June 30, 2024, the market value of our common stock held by non-affiliates exceeded $700.0 million. Consequently, we will be a large accelerated filer and will therefore cease to be a smaller reporting company effective December 31, 2024 and will no longer be able to rely on the scaled disclosure exemptions available to smaller reporting companies starting with our Quarterly Report on Form 10-Q for the three months ending March 31, 2025. As a result of this transition, we will be subject to certain disclosure and compliance requirements that apply to other public companies which did not previously apply to us due to our status as a smaller reporting company and expect to incur additional legal and financial compliance costs as a result.

As a public company in the U.S., we are required, pursuant to Section 404 of Sarbanes-Oxley to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting, and in connection with our transition to being a large accelerated filer, we expect that compliance with the auditor attestations requirements of Section 404(b) of the Sarbanes-Oxley Act beginning with the Annual Report on Form 10-K for the year ended December 31, 2024 will substantially increase our compliance costs. The controls and other procedures are designed to ensure that information required to be disclosed by us in the reports that we file with the SEC is disclosed accurately and is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms.

In the normal course of business our controls and procedures may become inadequate because of changes in conditions or the degree of compliance with these policies or procedures may deteriorate and material weaknesses in our internal control over financial reporting may be discovered. We may err in the design or operation of our controls, and all internal control systems, no matter how well designed and operated, can provide only reasonable assurance that the objectives of the control system are met. Because there are inherent limitations in all control systems, there can be no absolute assurance that all control issues have been or will be detected. If we are unable, or are perceived as unable, to produce reliable financial reports due to internal control deficiencies, investors could lose confidence in our reported financial information and operating results, which could result in a negative market reaction.

To fully comply with Section 404, we will need to retain additional employees to supplement our current finance staff, and we may not be able to do so in a timely manner, or at all. In addition, in the process of evaluating our internal control over financial reporting, we expect that certain of our internal control practices will need to be updated to comply with the requirements of Section 404 and the regulations promulgated thereunder, and we may not be able to do so on a timely basis, or at all. In the event that we are not able to demonstrate compliance with Section 404 in a timely manner, or are unable to produce timely or accurate financial statements, we may be subject to sanctions or investigations by regulatory authorities, such as the SEC or Nasdaq, and investors may lose confidence in our operating results and the price of our common stock could decline. Furthermore, if we are unable to certify that our internal control over financial reporting is effective and in compliance with Section 404, we may be subject to sanctions or investigations by regulatory authorities, such as the SEC or stock exchanges, and investors could lose confidence in the accuracy and completeness of our financial reports, which could hurt our business, the price of our common stock and our ability to access the capital markets.

Operating as a public company makes it more expensive for us to obtain directors' and officers' liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These factors could also make it more difficult for us to attract and retain qualified persons to serve on the Board of Directors, on committees of the Board of Directors, or as members of senior management.

If a restatement of our consolidated financial statements were to occur, our stockholders' confidence in the company's financial reporting in the future may be affected, which could in turn have a material adverse effect on our business and stock price.

If any material weaknesses in our internal control over financial reporting are discovered or occur in the future, our consolidated financial statements may contain material misstatements, and we could be required to restate our financial results. In addition, if we are unable to successfully remediate any future material weaknesses in our internal controls or if we are unable to produce accurate and timely financial statements, our stock price may be adversely affected, and we may be unable to maintain compliance with applicable stock exchange listing requirements.

We have not paid cash dividends in the past and do not expect to pay dividends in the future. Any return on investment may be limited to the value of our common stock.

We have never paid cash dividends on our common stock and do not anticipate paying cash dividends for the foreseeable future. The payment of dividends on our common stock will depend on earnings, financial condition, and other business and economic factors affecting us at such time as the Board of Directors may consider relevant. If we do not pay dividends, our common stock may be less valuable because a return on your investment will only occur if our stock price appreciates.

Because we are relying on the exemptions from corporate governance requirements as a result of being a "controlled company" within the meaning of the Nasdaq listing standards, you do not have the same protections afforded to stockholders of companies that are subject to such requirements.

Our Founder, Executive Chairman and Global Chief Scientific and Medical Officer, Dr. Soon-Shiong, and entities affiliated with him, control a majority of our common stock. As a result, we are a controlled company within the meaning of the Nasdaq listing standards. Under these rules, a company of which more than 50% of the voting power is held by an individual, a group or another company is a controlled company and may elect not to comply with certain Nasdaq corporate governance requirements, including (1) the requirement that a majority of the Board of Directors consist of independent directors and (2) the requirement that we have a Nominating and Corporate Governance Committee that is composed entirely of independent directors with a written charter addressing the committee's purpose and responsibilities. Accordingly, you do not have the same protections afforded to stockholders of companies that are subject to all of the Nasdaq corporate governance requirements. However, our Board of Directors is currently comprised of a majority of independent directors, and we currently have a Nominating and Corporate Governance Committee and the majority of the members of such committee are independent directors.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our share price and trading volume could decline.

The trading market for our common stock and the value of our warrants will depend on the research and reports that securities or industry analysts publish about us or our business. We do not have any control over these analysts. There can be no assurance that analysts will cover us or provide favorable coverage. If one or more of the analysts who cover us downgrade our stock or change their opinion of our stock, our share price would likely decline. If one or more of these analysts cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which could cause our share price or trading volume to decline.

Holders of our CVRs that are payable contingent upon us achieving certain milestones may not receive any further consideration.

In connection with our 2017 acquisition of Altor, we issued CVRs under which we agreed to pay the prior stockholders of Altor approximately $304.0 million of contingent consideration upon the successful regulatory approval of a BLA by the FDA, or foreign equivalent, for ANKTIVA by December 31, 2022, and approximately $304.0 million of contingent consideration upon calendar-year worldwide sales of ANKTIVA exceeding $1.0 billion prior to December 31, 2026, with amounts payable in cash or shares of our common stock or a combination thereof.

With respect to the regulatory milestone CVR agreement, the FDA approved our BLA in April 2024, which was after the milestone date set forth in such CVR agreement. The FDA did not approve our BLA on or before December 31, 2022, and therefore the regulatory milestone was not met, and the regulatory milestone CVR agreement terminated in accordance with its terms. With respect to the sales milestone CVR agreement, there can be no assurance that such sales milestone will be achieved. Accordingly, holders of our CVRs that are payable contingent upon us achieving the aforementioned milestones may not receive any further consideration. Further, failure to achieve the milestones set forth in our CVR agreements may give rise to disputes with the holders of such CVRs. For example, the shareholder representative for the holders of regulatory milestone CVRs has notified us that it is exploring, and may intend to pursue, claims on behalf of such holders based on our alleged failure to use commercially reasonable efforts to secure FDA approval of the BLA on or before the December 31, 2022 milestone date, and the parties are currently engaged in an arbitration seeking to compel us to produce additional documents related to our efforts. The arbitration does not seek monetary relief. To the extent further claims are filed regarding our CVR agreements, we could be subject to monetary awards that may be substantial notwithstanding our vigorous defense, and even if such claims are not successful, litigation could result in substantial costs, adversely impact our reputation, and divert management's attention and resources, which could have a material adverse effect on our business, operating results, and financial condition.

We are not subject to the provisions of Section 203 of the DGCL, which could negatively affect your investment.

We elected in our Amended and Restated Certificate of Incorporation to not be subject to the provisions of Section 203 of the DGCL. In general, Section 203 prohibits a publicly held Delaware corporation from engaging in a business combination with an interested stockholder for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner. A business combination includes a merger, asset sale, or other transaction resulting in a financial benefit to the interested stockholder. An interested stockholder is a person who, together with affiliates and associates, owns (or, in certain cases, within three years prior, did own) 15% or more of the corporation's voting stock. Our decision not to be subject to Section 203 will allow, for example, our Founder, Executive Chairman and Global Chief Scientific and Medical Officer (who, with members of his immediate family and entities affiliated with him, owned, in the aggregate, approximately 76.2% of our common stock outstanding as of December 31, 2024) to transfer shares in excess of 15% of our voting stock to a third-party free of the restrictions imposed by Section 203. This may make us more vulnerable to takeovers that are completed without the approval of our Board of Directors and/or without giving us the ability to prohibit or delay such takeovers as effectively.

Some provisions of our charter documents and Delaware law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws, as well as provisions of Delaware law, could make it more difficult for a third party to acquire us or increase the cost of acquiring us, even if doing so would benefit our stockholders. These provisions include:

- a requirement that special meetings of stockholders be called only by the board of directors, president or chief executive officer;
- advance notice requirements for stockholder proposals and nominations for election to the board of directors; and
- the authority of the board of directors to issue preferred stock on terms determined by the board of directors without stockholder approval and which preferred stock may include rights superior to the rights of the holders of common stock.

These anti-takeover provisions and other provisions in our Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws could make it more difficult for stockholders or potential acquirers to obtain control of our Board of Directors or initiate actions that are opposed by the then-current Board of Directors and could also delay or impede a merger, tender offer, or proxy contest involving our company. These provisions could also discourage proxy contests and make it more difficult for you and other stockholders to elect directors of your choosing or cause us to take other corporate actions you desire. Any delay or prevention of a change of control transaction or changes in our Board of Directors could cause the market price of our common stock to decline.

Claims for indemnification by our directors and officers may reduce our available funds to satisfy successful third-party claims against us and may reduce the amount of money available to us.

Our Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws provide that we will indemnify our directors and officers, in each case to the fullest extent permitted by Delaware law. In addition, as permitted by Section 145 of the DGCL, our Amended and Restated Bylaws, and our indemnification agreements that we have entered into with our directors and officers provide that:

- We will indemnify our directors and officers for serving us in those capacities or for serving other business enterprises at our request, to the fullest extent permitted by Delaware law. Delaware law provides that a corporation may indemnify such person if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the registrant and, with respect to any criminal proceeding, had no reasonable cause to believe such person's conduct was unlawful.
- We may, in our discretion, indemnify employees and agents in those circumstances where indemnification is permitted by applicable law.
- We are required to advance expenses, as incurred, to our directors and officers in connection with defending a proceeding, except that such directors or officers shall undertake to repay such advances if it is ultimately determined that such person is not entitled to indemnification.

- We are not obligated pursuant to our Amended and Restated Bylaws to indemnify a person with respect to proceedings initiated by that person against us or our other indemnitees except with respect to proceedings authorized by our Board of Directors or brought to enforce a right to indemnification.
- The rights conferred in our Amended and Restated Bylaws are not exclusive, and we are authorized to enter into indemnification agreements with our directors, officers, employees and agents and to obtain insurance to indemnify such persons.
- We may not retroactively amend our bylaw provisions to reduce our indemnification obligations to directors, officers, employees and agents.

To the extent that a claim for indemnification is brought by any of our directors or officers, it would reduce the amount of funds available for use in our business.

Our bylaws provide that the Delaware Court of Chancery is the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or other employees.

Our amended and restated bylaws provides that the Delaware Court of Chancery (or, if the Delaware Court of Chancery does not have jurisdiction, the federal district court for the District of Delaware) is the sole and exclusive forum for any state law claims for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a breach of fiduciary duty owed by any of our directors, officers or other employees or our stockholders, (iii) any action asserting a claim against us arising pursuant to any provisions of the DGCL, or as to which the DGCL confers jurisdiction on the Delaware Court of Chancery, our amended and restated certificate of incorporation or our bylaws (including the interpretation, validity or enforceability thereof), or (iv) any action asserting a claim against us that is governed by the internal affairs doctrine; provided, that these choice of forum provisions do not apply to suits brought to enforce a duty or liability created by the Securities Act, the Exchange Act, or any other claim for which the federal courts have exclusive jurisdiction. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Our amended and restated bylaws provide that the federal district courts are the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. The choice of forum provision 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. If a court were to find the choice of forum provision contained in the bylaws 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. Any person or entity purchasing or otherwise acquiring any interest in shares of our common stock shall be deemed to have notice of and to have consented to the provisions of our bylaws described above.

ITEM 1B. UNRESOLVED STAFF COMMENTS.

None.

ITEM 1C. CYBERSECURITY.

Risk Assessment and Management

We regularly assess risks from cybersecurity threats; monitor our information systems for potential vulnerabilities; and test those systems pursuant to our cybersecurity policies, processes, and practices, which are integrated into our overall risk management program. To protect our information systems from cybersecurity threats, we use various security tools that are designed to help identify, escalate, investigate, resolve, and recover from security incidents in a timely manner.

The company has an ERM program to identify, evaluate, and manage risks. Cybersecurity risks are evaluated alongside other critical business risks under the ERM program to align cybersecurity efforts with the company's broader business goals and objectives. We believe that integrating cybersecurity risks into our ERM program fosters a proactive and holistic approach to cybersecurity, which helps safeguard the company's operations, financial condition, and reputation in an ever-evolving threat landscape.

The company maintains a cybersecurity program that is designed to identify, protect from, detect, respond to, and recover from cybersecurity threats and risks, and protect the confidentiality, integrity, and availability of its information systems, including the information residing on such systems.

Cybersecurity threats, including those resulting from any previous cybersecurity incidents, have not materially affected the company, including our business strategy, results of operations, or financial condition. We do not believe that cybersecurity threats resulting from any previous cybersecurity incidents of which we are aware are reasonably likely to materially affect our company. See Item 1A. *"Risk Factors—Our systems, infrastructure or data, or those used by our CROs, CMOs, clinical sites or other contractors or consultants, may or may be perceived to fail or suffer a cyberattack, security breach or other incident, including a breakdown or compromise of the confidentiality, integrity and availability of our systems, networks or data, which could adversely affect the operation of our business and reputation"* for more information regarding cybersecurity risks and the potential impact on the company.

Incident Response

The company has a dedicated incident management team responsible for managing and coordinating its cybersecurity incident response efforts. This team also collaborates closely with other teams in identifying, protecting from, detecting, responding to, and recovering from cybersecurity incidents. Cybersecurity incidents that meet certain thresholds are escalated to the executive incident team and cross-functional teams on an as-needed basis for support and guidance. Additionally, this team tracks cybersecurity incidents to help identify and analyze them. The company's incident response team partners with other key stakeholders as appropriate to respond to cybersecurity incidents. The company maintains a cybersecurity and incident response program to prepare for and respond to cybersecurity incidents, which includes standard processes for reporting and escalating cybersecurity incidents to the executive incident team. Additionally, the company conducts at least one incident response test exercise on an annual basis, where members of a cross-functional team engage in a simulated incident scenario.

Governance

Board Oversight Role

Our Board of Directors oversees our risk management process, including as it pertains to cybersecurity risks, directly and through its committees. The Audit Committee (the Committee) of the Board of Directors oversees our cybersecurity and data privacy. The Committee meets periodically to review and discuss with management risks relating to significant cybersecurity matters and concerns involving the company, including information security, data privacy, backup of information systems and related regulatory matters and compliance. The Committee regularly reports to the Board of Directors with respect to the Committee's activities and recommendations, including those relating to cybersecurity matters and concerns. The CIO provides quarterly reports to the Committee on information security matters, including the adequacy and effectiveness of the company's information security policies and practices and the internal controls regarding information security, and notifies the chairperson of the Committee as soon as practicable of significant information security matters and concerns as they arise.

Management's Role

The company has a dedicated cybersecurity organization within its technology department that focuses on current and emerging cybersecurity matters. The company's cybersecurity function is led by the company's director of information security, who reports to the CIO. The director of information security and CIO (collectively, the Cybersecurity Leaders) are actively involved in assessing and managing cybersecurity risks, and are responsible for implementing cybersecurity policies, programs, procedures, and strategies. The responsibilities and relevant experience of each of the Cybersecurity Leaders are as follows:

The CIO provides leadership for the company's technology department. She holds a Bachelor of Science, Communication from Arizona State University, has served in various roles in information technology for over 25 years, holds multiple certifications, and has been actively involved in the information security and cybersecurity domains for over 20 years.

The director of information security is responsible for all aspects of cybersecurity across the company's locations and data centers, including security engineering, security operations, incident response, threat intelligence, risk and compliance, and vulnerability management. He holds a Bachelor of Science in Business Administration, Management Information Systems from the University of Arizona, holds various certifications, and has served in various roles in information technology for over 25 years at numerous technology companies and consulting firms.

The company's cybersecurity department is comprised of teams that engage in a range of cybersecurity activities such as threat intelligence, security architecture, and incident response. These teams conduct vulnerability management and penetration testing to identify, classify, prioritize, remediate, and mitigate vulnerabilities. Leaders from each team regularly meet with the Cybersecurity Leaders to provide visibility to major issues and seek alignment with strategy. As discussed above, the company's cybersecurity incident response plan includes standard processes for reporting and escalating cybersecurity incidents to senior management. Cybersecurity incidents that meet certain thresholds are escalated to the Cybersecurity Leaders and cross-functional teams on an as-needed basis for support and guidance. The company's incident response team also coordinates with external legal advisors, communication specialists, and other key stakeholders.

Use of Third Parties

Cybersecurity Service Providers and Third-Party Consultants

The company engages cybersecurity consultants and other third parties to assess and enhance its cybersecurity practices. These third parties conduct assessments and penetration testing to identify weaknesses and recommend improvements. Additionally, the company leverages a number of third-party tools and technologies as part of its efforts to enhance cybersecurity functions, including a managed security service provider to augment the company's internal resources, an endpoint detection and response system for continuous monitoring, detection, and response capabilities, and a security information and event management solution to automate real-time threat detection, investigation, and prioritization of high-fidelity alerts.

Oversight of Third-Party Service Providers

The company also uses third-party service providers to support its operations and many of its technology initiatives, and evaluates its third-party service providers from a cybersecurity risk perspective, which may include an assessment of that service provider's cybersecurity posture or a recommendation of specific mitigation controls. Following such evaluation, the company determines and prioritizes service provider risk based on the potential threat impact and likelihood, and such risk determination drives the level of due diligence and ongoing compliance monitoring required for each service provider.

ITEM 2. PROPERTIES.

We lease property in multiple facilities across the U.S. and Italy, including facilities located in El Segundo and Culver City, CA that are leased from related parties. See Note 13 *"Related-Party Agreements"* of the "Notes to Consolidated Financial Statements" that appears in Part II, Item 8. "Financial Statements and Supplementary Data" of this Annual Report for more information about our related-party leases.

The following table summarizes our principal properties under lease as of December 31, 2024:

Location	Expiration Year (1)	Approximate Rentable Square Feet (2)	Primary Function(s)
United States			
Dunkirk, NY	2031	409,000	Future Manufacturing Facility
El Segundo, CA	2026 – 2029	132,136	Laboratory – Research & Manufacturing
Louisville, CO	2025	50,838	Laboratory – Research
Culver City, CA	Month to Month	46,330	Laboratory – Research & Manufacturing
San Diego, CA	2030	44,681	Laboratory – Research & Corporate Office
Summit, NJ	2028	11,256	Office - Regulatory Affairs
Woburn, MA	2025	8,153	Laboratory – Research & Office
Seattle, WA	2025	5,527	Laboratory – Research
International			
Italy	2027 – 2030	15,748	Laboratory – Research & Office

(1) Expiration years shown are per the lease agreements in effect as of December 31, 2024 and do not reflect contractual options to extend the term of the lease available to us under the lease agreements. For locations with multiple leases, the first and last expiration year are shown.

(2) Amounts shown represent the total approximate rentable square feet for all buildings located in each city.

We believe that our existing facilities are adequate to meet our current and future needs and that we will be able to renew existing leases and obtain additional commercial space as needed.

ITEM 3. LEGAL PROCEEDINGS.

From time to time, we may be involved in various claims and legal proceedings relating to claims arising out of our operations. We are not currently a party to any legal proceedings that, in the opinion of our management, are likely to have a material adverse effect on our business. If we are served with any such complaints, we will assess at that time any contingencies for which we may need to reserve. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources, and other factors.

Shenzhen Beike Biotechnology Co. Ltd. Arbitration

In 2020, we received a Request for Arbitration before the International Chamber of Commerce, International Court of Arbitration. The arbitration relates to a license, development, and commercialization agreement that Altor entered into with Beike in 2014, which agreement was amended and restated in 2017, pursuant to which Altor granted to Beike an exclusive license to use, research, develop and commercialize products based on ANKTIVA in China for human therapeutic uses. In the arbitration, Beike is asserting a claim for breach of contract under the license agreement. Among other things, Beike alleges that we failed to use commercially reasonable efforts to deliver to Beike materials and data related to ANKTIVA. Beike is seeking specific performance and declaratory relief for the alleged breaches. On September 25, 2020, the parties entered into a standstill and tolling agreement (standstill agreement) under which, among other things, the parties affirmed they will perform certain of their obligations under the license agreement by specified dates and agreed that all deadlines in the arbitration are indefinitely extended. The standstill agreement could be terminated by any party on ten calendar days' notice, and upon termination, the parties had the right to pursue claims arising from the license agreement in any appropriate tribunal. On March 20, 2023, we terminated the standstill agreement, and on April 11, 2023, Beike served an amended Request for Arbitration. We served an Answer and Counterclaims on May 19, 2023. Beike served a Reply to our counterclaims on June 21, 2023. Beike served its Statement of Claim on March 22, 2024, and the company served its Statement of Defense and Counterclaim on June 21, 2024, and Beike served its Statement of Defense to the Counterclaim on August 2, 2024. After the parties completed discovery, Beike served its Reply and Defense to Counterclaim on January 17, 2025. The hearing in the arbitration is scheduled to begin on June 9, 2025. Given that the proceeding is in the pre-hearing stages, it remains too early to evaluate the likely outcome of the case or to estimate any range of potential loss. We believe the claims asserted against the company lack merit and intend to defend the case, and to pursue our counterclaims, vigorously.

Securities Class Action

On June 30, 2023, a putative securities class action complaint, captioned *Salzman v. ImmunityBio, Inc. et al.*, No. 3:23-cv-01216-GCP-VET, was filed in the United States District Court for the Southern District of California against the company and three of its officers and/or directors, asserting violations of Sections 10(b) and 20(a) of the Exchange Act. Stemming from the company's disclosure on May 11, 2023 that it had received an FDA CRL stating, among other things, that it could not approve the company's BLA for its then product candidate, ANKTIVA with BCG for the treatment of adult patients with BCG-unresponsive NMIBC with CIS with or without papillary tumors, in its present form due to deficiencies related to its pre-license inspection of the company's third-party CMOs, the complaint alleges that the defendants had previously made materially false and misleading statements and/or omitted material adverse facts regarding its third-party CMOs and the prospects for regulatory approval of the BLA. The complaint did not specify the amount of damages being sought. On September 27, 2023, the court appointed a lead plaintiff, approved their selection of lead counsel, and re-captioned the case *In re ImmunityBio, Inc. Securities Litigation,* No. 3:23-cv-01216. On November 17, 2023, the lead plaintiff filed an amended complaint, which named the same defendants and asserted the same claims as the previous complaint. On January 8, 2024, the defendants filed a motion to dismiss the amended complaint. On June 20, 2024, the court issued an order granting in part and denying in part the motion to dismiss. On July 16, 2024, the lead plaintiff notified the court that he would proceed with his current pleading, and the defendants answered the complaint on August 29, 2024. On January 25, 2025, following a mediation and the parties' agreement in principle to settle the securities class action for $10.5 million, the lead plaintiff filed an unopposed motion for preliminary approval of class action settlement. The settlement is subject to preliminary and final approval by the U.S. District Court for the Southern District of California. A preliminary approval hearing is scheduled for March 7, 2025.

As a result of the foregoing, the company recorded legal settlement expense of $10.5 million in *selling, general and administrative expense,* on the consolidated statement of operations during the year ended December 31, 2024 and a corresponding amount in *accrued expenses and other liabilities*, on the consolidated balance sheet. The company believes that approximately $6.0 million of this amount will be paid by the company's insurers, which will be recorded upon receipt.

To the extent the court does not grant final approval of the settlement described above, the company is unable to estimate a range of loss, if any, that could result were there to be an adverse final decision in this action. In this event and if an unfavorable outcome were to occur, it is possible that the impact could be material to the company's results of operations in the period(s) in which any such outcome becomes probable and estimable.

Altor BioScience, LLC, and NantCell, Inc. Matters Against Dr. Hing Wong and HCW Biologics, Inc.

On December 23, 2022, Altor and NantCell filed an arbitration demand against Dr. Hing Wong, former CEO of Altor and NantCell. The demand asserts claims for breach of Dr. Wong's contracts with the companies, breach of the covenant of good faith and fair dealing, conversion, fraudulent concealment, unjust enrichment, breach of fiduciary duty, and replevin. The same day, Dr. Wong filed an arbitration demand seeking a declaratory judgment finding that Dr. Wong is not liable to Altor or NantCell for any of their claims. The parties agreed to consolidate the arbitration filings in one proceeding, and on January 23, 2023, Dr. Wong filed an Answering Statement denying the claims.

Also, on December 23, 2022 Altor and NantCell filed a complaint in the United States District Court for the Southern District of Florida against HCW, Dr. Wong's new company. Altor's and NantCell's complaint asserts claims for misappropriation of trade secrets under both Florida and federal law, inducement of breach of contract, tortious interference with contractual relations, inducement of breach of fiduciary duty, conversion, unjust enrichment, replevin, request for assignment of patents and patent applications, and establishment of a constructive trust. On January 31, 2023, HCW filed motions to compel arbitration of Altor's and NantCell's claims, or in the alternative to stay or dismiss them. Altor and NantCell filed an opposition to the motions on February 14, 2023, and HCW filed reply papers on February 21, 2023. At a hearing on April 18, 2023, the court heard argument and requested supplemental briefing. After the hearing, the parties reached an agreement to consolidate all claims in a single arbitration proceeding. On May 1, 2023, we filed our arbitration demand asserting the same claims against HCW that were asserted in the federal court complaint. On May 15, 2023, HCW filed an Answering Statement denying the claims. The hearing in the consolidated arbitration took place from May 20, 2024 to May 30, 2024.

On July 13, 2024, we entered into a Settlement with HCW and Dr. Hing Wong to resolve the claims asserted in the consolidated arbitration and related matters. Under the terms of the Settlement, in part and for no monetary consideration from ImmunityBio, HCW transferred and assigned to ImmunityBio molecules (along with other related assets, including master cell banks, clinical trial protocols, inventory and FDA documents), controlled by HCW that were generated through the use of a TF Platform related to the human TGF-β receptor and TGF-β traps, including, without limitation, HCW9218, HCW9219, HCW9209 and any derivatives thereof or therefrom, including assignment of all patents, know-how and all other intellectual property existing as of the Settlement effective date and thereafter that is necessary or reasonably useful for the exploitation of such TGF-β molecules, with the exception that future reasonably useful intellectual property is the subject of a non-exclusive license to ImmunityBio. For indications outside of oncology, ImmunityBio has agreed to grant an exclusive license back to HCW for the transferred intellectual property for TGF-β products, and a non-exclusive license for neoadjuvant ovarian cancer, subject to certain requirements.

In addition, the Settlement provides to ImmunityBio a worldwide, perpetual, irrevocable, fully paid-up, royalty-free, exclusive license to exploit fusion proteins, molecules and/or antibodies created utilizing the TF Platform directed to the receptors of PDL-1, IL-7, IL-12, IL-15, IL-18, and IL-21 in the oncology field. Furthermore, the Settlement provides additional license terms including, without limitation, a non-exclusive license to ImmunityBio to exploit HCW9201, another fusion protein, and the anti-tissue factor based antibody HCW9101 and the linked resins to manufacture and purify the fusion proteins described above, as well as a right of first refusal for ImmunityBio with respect to any other fusion protein developed by HCW using the TF Platform going forward.

Pursuant to the Settlement, the parties agreed to mutual, full and complete releases. On December 23 and 24, 2024, the company dismissed the consolidated arbitration claims and a related action in the Delaware Court of Chancery in light of the Settlement.

Van Luven, Barbieri and Shin Derivative Actions

On October 29, 2024, a shareholder derivative action was filed in the United States District Court for the Southern District of California against the members of our Board of Directors and certain officers, captioned *Van Luven v. Soon-Shiong et al.*, Case No. 3:24-cv-02014-GPCL-VET. The plaintiff purports to bring the action derivatively on behalf of ImmunityBio, and ImmunityBio is a nominal defendant to the action. Stemming from the company's May 11, 2023 disclosure that it had received an FDA CRL stating, among other things, that it could not approve the company's BLA for its then product candidate, ANKTIVA with BCG for the treatment of adult patients with BCG-unresponsive NMIBC with CIS with or without papillary tumors, in its present form due to deficiencies related to its pre-license inspection of the company's third-party CMOs, the derivative complaint alleges that the individual defendants authorized or permitted materially false and misleading statements and/or omitted material adverse facts regarding ImmunityBio's third-party CMOs and the prospects for regulatory approval of the ANKTIVA BLA. The derivative complaint asserts claims for violations of Section 14(a) of the Exchange Act as well as claims for breach of fiduciary duty, unjust enrichment, and waste of corporate assets. The derivative complaint seeks unspecified damages on behalf of the company, disgorgement or restitution, declaratory relief, and an award of costs and expenses to the derivative plaintiff, including attorneys' fees. The court has entered an order extending the defendants' deadline to respond to the complaint to April 18, 2025.

On February 25, 2025, a second shareholder derivative action was filed in the United States District Court for the Southern District of California against certain members of our Board of Directors and certain officers, captioned *Barbieri v. Soon-Shiong, et al*., Case No. 3:25-cv-00416-AGS-JLB. The plaintiff purports to bring the action derivatively on behalf of ImmunityBio, and ImmunityBio is a nominal defendant in the action. This lawsuit asserts substantially similar claims and allegations as *Van Luven*.

On February 26, 2025, a third shareholder derivative action was filed in the United States District Court for the Southern District of California against certain current and former members of our Board of Directors and certain officers, captioned *Shin v. Soon-Shiong, et al.*, Case No. 3:25-cv-00423-JAH-DDL. The plaintiff purports to bring the action derivatively on behalf of ImmunityBio, and ImmunityBio is a nominal defendant in the action. This lawsuit asserts substantially similar claims and allegations as Van *Luven*.

Carlson Derivative Action

On November 20, 2024, a shareholder derivative action was filed in the Delaware Court of Chancery against the company's Founder, Executive Chairman, Global Chief Scientific and Medical Officer and principal stockholder, Dr. Soon-Shiong, certain affiliates of Dr. Soon-Shiong, certain other members of management, and members of the company's Board of Directors who serve on the Board of Directors' Related Party Transaction Committee, captioned *Carlson v. Soon-Shiong, et al.,* Case No. 2024-1195-VCL. The plaintiff purports to bring the action derivatively on behalf of ImmunityBio, and ImmunityBio is a nominal defendant to the action. The plaintiff alleges that the previously disclosed September 2023 financing transactions between the company and Dr. Soon-Shiong and his affiliates were not fair to the company. In particular, the plaintiff alleges that the transactions were timed to benefit Dr. Soon-Shiong and his affiliates during a temporary decline in the company's stock price, resulting in an artificially low conversion price for certain convertible promissory notes that were among the transactions, when defendants knew the company's stock price would increase following the company's imminent resubmission of a BLA for, and the subsequent FDA approval of, ANKTIVA with BCG for the treatment of adult patients with BCG-unresponsive NMIBC with CIS with or without papillary tumors. The complaint alleges that defendants breached their fiduciary duties by entering into these transactions at that time and on those terms, thereby unjustly enriching Dr. Soon-Shiong and his affiliates. The derivative complaint seeks unspecified damages on behalf of the company, corporate governance changes with respect to related-party transactions, and an award of costs and expenses to the derivative plaintiff, including attorneys' fees. On February 17, 2025, the defendants filed a motion to dismiss the complaint.

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 under the ticker symbol "IBRX" on the Nasdaq Global Select Market.

Holders of Record

As of February 27, 2025, there were approximately 80 stockholders of record of our common stock. The actual number of stockholders is greater than the number of record holders and includes stockholders who are beneficial owners but whose shares are held in "street name" by brokers and other nominees. The number of stockholders of record also does not include stockholders whose shares may be held in trust or by other entities.

Dividend Policy

We have never paid cash dividends on our common stock and do not anticipate paying cash dividends on our common stock for the foreseeable future. The payment of dividends on our common stock will depend on earnings, financial condition and other business and economic factors affecting us at such time as the Board of Directors may consider relevant.

Securities Authorized for Issuance Under Equity Compensation Plans

The following table sets forth information regarding our equity compensation plans in effect as of December 31, 2024 (including upon the exercise of stock options and the vesting of RSUs):

	Equity Compensation Plan Information		
Plan Category	Number of Securities to be Issued upon Exercise of Outstanding Options, Warrants and Rights (a)	Weighted-average Exercise Price of Outstanding Options, Warrants and Rights (b)	Number of Securities Remaining Available for Future Issuance under Equity Compensation Plans (Excluding Securities Reflected in Column (a)) (c)
Equity compensation plans approved by security holders (1), (2), (3), (4)	21,353,009	$ 8.00	25,433,332
Equity compensation plan not approved by security holders	—		—
Total	21,353,009		25,433,332

(1) The equity compensation plans approved by security holders are the 2014 Plan and the 2015 Plan. The 2014 Plan has terminated as to future grants. The amount shown in Column (a) with respect to the 2014 Plan includes 110,020 shares issuable upon the exercise of vested stock options. The amount shown in Column (a) with respect to the 2015 Plan includes 15,018,712 shares issuable upon the exercise of vested stock options and 4,007,636 shares issuable upon the vesting of RSUs.

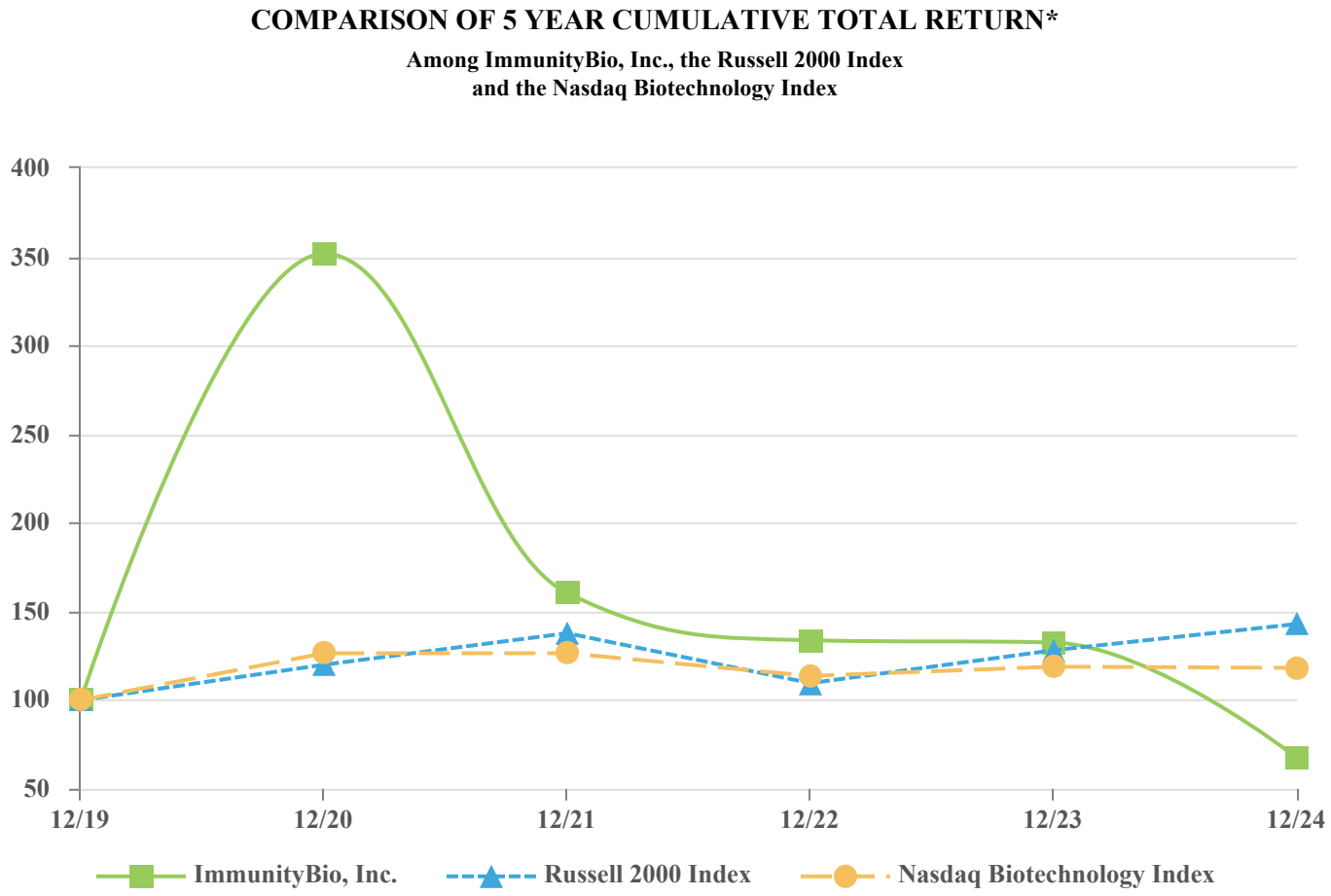
(2) The NC 2015 Plan was approved by security holders in conjunction with the Merger. The NC 2015 Plan has terminated as to future grants. The amount shown in Column (a) with respect to this plan includes 278,856 shares issuable upon the exercise of vested stock options and 1,937,785 shares issuable upon the vesting of RSUs.

(3) The amount shown in Column (b) is the weighted-average exercise price for stock options outstanding.

(4) The amount shown in Column (c) is the number of shares available for future grants under the 2015 Plan.

Stock Performance Graph

The following graph compares the cumulative total return on our common stock, the Russell 2000 Index, and the Nasdaq Biotechnology Index over the five-year period ending December 31, 2024. The graph assumes that $100 was invested on December 31, 2019 in our common stock or the comparative indices, including reinvestment of dividends. The returns shown are based on historical results and are not indicative of, or intended to forecast, future performance of our common stock or the comparative indices. This performance graph shall not be deemed filed for purposes of Section 18 of the Exchange Act or incorporated by reference into any filing of ImmunityBio, Inc. under the Securities Act.



Recent Sales of Unregistered Securities

None.

Issuer Purchases of Equity Securities

No shares of our common stock were repurchased during the three months ended December 31, 2024 under the 2015 Share Repurchase Program. As of December 31, 2024, $18.3 million remained authorized to use for share repurchases under the program. See Note 15 *"Stockholders' Deficit"* of the "Notes to Consolidated Financial Statements" that appears in Part II, Item 8. "Financial Statements and Supplementary Data" of this Annual Report for more information regarding the 2015 Share Repurchase Program.

ITEM 6. RESERVED

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

The following discussion and analysis of our financial condition and results of operations should be read together with the description of our business that appears in Part I, Item 1. "Business" and the consolidated financial statements and related notes thereto in Part II, Item 8. "Financial Statements and Supplementary Data" of this Annual Report. This discussion contains forward-looking statements as a result of many factors, including those set forth under Part I, Item 1. "Business—Forward-Looking Statements" and Item 1A. "Risk Factors" and elsewhere in this Annual Report. These statements are based on our management's beliefs and assumptions and on information currently available to our management. Actual results could differ materially from those discussed in or implied by such forward-looking statements. Factors that could cause or contribute to these differences include those discussed below and elsewhere in this Annual Report, particularly in Part I, Item 1A. "Risk Factors." Except as required by law, we do not undertake any responsibility to update any of these factors or to announce publicly any revisions to any of the forward-looking statements contained in this or any document, whether as a result of new information, future events, or otherwise.

ImmunityBio is a vertically-integrated commercial stage biotechnology company developing next-generation therapies that bolster the natural immune system to defeat cancers and infectious diseases. The company's range of immunotherapy platforms, alone and together, act to drive an immune response with the goal of creating durable immune memory generating safe protection against disease. We are applying our science and platforms to treating cancers, including the development of potential cancer vaccines, as well as developing immunotherapies and cell therapies that we believe sharply reduce or eliminate the need for standard high-dose chemotherapy. These platforms and their associated product candidates are designed to be more effective, accessible, and easily administered than current standards of care in oncology and infectious diseases.

Our Approved Product – ANKTIVA

Our lead biologic product ANKTIVA is a novel first-in-class IL-15 receptor superagonist antibody-cytokine fusion protein. On April 22, 2024, the FDA approved our product, ANKTIVA with BCG for the treatment of adult patients with BCG-unresponsive NMIBC with CIS with or without papillary tumors (the "approved product"). ANKTIVA was approved with a label indicating an immunological mechanism of action which proliferates and activates NK, CD8+ and memory T cells without the proliferation of immunosuppressive T-reg cells leading to the establishment of memory T cells. We began commercial distribution of our approved product in May 2024.

We believe there is potential for ANKTIVA to become a therapeutic foundation across all phases of treatment, including in adjunctive therapy, to amplify, reactivate or extend the efficacy of standard of care. ANKTIVA is being clinically evaluated in multiple oncology indications. We believe that other oncology indications with registration potential for ANKTIVA include other types of NMIBC (BCG-unresponsive papillary, BCG-naïve CIS and BCG-naïve papillary), lung, colorectal, prostate and ovarian cancers, and GBM and NHL.

Data from multiple clinical trials suggest ANKTIVA has potential to enhance the activity of therapeutic mAbs, including CPIs (e.g., pembrolizumab/Keytruda), across a wide range of tumor types, including lung cancer. Further, ANKTIVA has been observed to increase lymphocyte count in healthy adults, making it a potential therapy to rescue lymphopenia. We are also exploring or pursuing several other studies of ANKTIVA in combination with our other product candidates, including in prostate cancer (ANKTIVA in combination with hAd5 PSA), colon cancer (ANKTIVA in combination with hAd5 TriAd), and NHL (ANKTIVA in combination with rituximab). We are also exploring ANKTIVA in infectious diseases, including HIV and long COVID.

Significant Developments

The following is a summary of selected significant developments affecting our business that occurred since the filing of our Quarterly Report dated September 30, 2024 with the SEC on November 12, 2024:

- ANKTIVA received a J-code assigned by the CMS in the U.S. for ANKTIVA, which became effective January 1, 2025.
- With a permanent J-code awarded in January 2025, our February 2025 ANKTIVA unit sales volume grew 97% over unit sales volume in December 2024 and 67% over unit sales volume in January 2025.
- We completed the submission of MAAs for the treatment of patients with BCG-unresponsive NMIBC with CIS with or without papillary tumors for ANKTIVA in combination with BCG to the MHRA in the UK in November 2024 and to the EMA in the EU in December 2024. Both MAAs were accepted for review, with the potential for approval in the UK and EU by 2026.
- In collaboration with Serum Institute, and in connection with our exclusive global supply arrangement that we announced during 2024, in February 2025 the FDA authorized an EAP allowing us to provide rBCG developed by Serum Institute to urologists to address the TICE BCG shortage in any settings where TICE BCG is approved, and we are also testing rBCG in an FDA-approved trial in the U.S. Serum Institute's GMP capacity to manufacture large-scale volumes of rBCG, already tested for safety and efficacy in clinical trials in Europe in subjects with NMIBC, aims to address the shortage of TICE BCG, which we believe will help to ensure a reliable supply for patients in need. We expect to begin shipments of rBCG pursuant to the EAP during the first quarter of 2025.
- In January 2025, we announced a collaboration and supply agreement with BeiGene, Ltd. (to be renamed to BeOne Medicines, Ltd.) to conduct a confirmatory randomized Phase 3 clinical trial combining BeOne's tislelizumab, a PD-1 CPI, and ANKTIVA in participants with advanced or metastatic NSCLC who have acquired resistance to immune CPI therapy.
- On February 27, 2025, the FDA granted us RMAT designation for ANKTIVA and CAR-NK (PD-L1 t-haNK) in combination with standard-of-care chemotherapy/radiotherapy indicated for the reversal of lymphopenia and treatment of multiply relapsed locally advanced or metastatic pancreatic cancer. This RMAT designation follows clinical data of ALC and significant overall survival correlations in QUILT trials across multiple tumor types including third-line or greater metastatic pancreatic cancer, checkpoint relapsed NSCLC, and supportive data from healthy volunteers. The reversal of lymphopenia by our IL-15 receptor superagonist is consistent with the mechanism of action of ANKTIVA demonstrating proliferation and activation of NK cells, CD4+ T cells, CD8+ T cells and memory T cells without upregulation of suppressive T-reg cells and approved in the ANKTIVA label (approved for the treatment of adult patients with BCG-unresponsive NMIBC with CIS with or without papillary tumors). We intend to submit a BLA for the indication of reversal of lymphopenia in patients receiving standard of care chemotherapy and/or radiation and for the treatment of locally advanced or metastatic pancreatic cancer which includes the first-in-class CAR-NK (PD-L1 t-haNK), and to provide data from fully enrolled clinical trials in metastatic pancreatic cancer (QUILT 88) and in checkpoint relapsed NSCLC (QUILT 3055, NSCLC Cohort) patients, as well as lymphopenia reversal across multiple tumor types (QUILT 3055, all Cohorts), with supportive data of lymphocyte proliferation in healthy volunteers (QUILT 1004). In addition, we intend to file an EAP for ANKTIVA and PD-L1 t-haNK in combination with standard of care chemotherapy/radiotherapy and to submit the protocol to the FDA.

Our Pipeline

Our proprietary platforms for the development of biologic products and product candidates include: (i) cytokine fusion proteins, (ii) vaccine vectors, and (iii) cell therapies. As of December 2024, our platforms have generated nine first-in-human therapeutic agents (including one agent approved by the FDA) that are currently or planned to be studied in clinical trials in liquid and solid tumors. These indications are among the most frequent and lethal cancer types and where there are high failure rates for existing standards of care or no available effective treatment. We are constantly monitoring and prioritizing clinical development based upon the availability of our resources and the efficacy and market developments of our competitors' products and product candidates, among other factors.

Our platforms and their associated product and product candidates are designed to attack cancer and infectious pathogens by activating both the innate immune system, including NK cells, dendritic cells, and macrophages, as well as the adaptive immune system comprising B and T cells, in an orchestrated manner. The goal of this potentially best-in-class approach is to generate immunogenic cell death thereby eliminating rogue cells from the body whether they are cancerous or virally-infected. Our ultimate goal is to overcome the limitations of current treatments, such as CPIs, by turning immunologically cold, MHC-deficient tumors into hot tumors, and/or reducing the need for standard high-dose chemotherapy in cancer by employing a coordinated approach to establish "immunological memory" that confers long-term benefit for the patient.

Operating Results

Until April 2024, we had no clinical products approved for commercial sale and thus had not generated any revenue from therapeutic and vaccine product candidates that are or were under development. Now that we have received FDA approval for ANKTIVA, we have begun to generate revenue although we expect it to take some time to generate significant revenue from our approved product and we can provide no assurance when, or if, this will occur. We began commercial distribution of our approved product in May 2024; however, we can provide no assurance with respect to our future revenues, market acceptance, reimbursement from third-party payors, or the profitability of our approved product or any other product candidate for which we may obtain approval. We do not expect additional revenue from our other product candidates unless and until we obtain regulatory approval of and commercialize any of our other product candidates, and we do not know when, or if, this will occur.

We expect to continue to incur significant expenses as we seek to expand our business, including commercializing our approved product, seeking regulatory approvals, conducting research and development across multiple therapeutic areas, participating in clinical trial activities, continuing to acquire or in-license technologies, maintaining, protecting and expanding our intellectual property, and increasing our manufacturing capabilities. Furthermore, the timing and magnitude of our approved product sales and revenue remain uncertain and may take a significant amount of time to materialize, if ever.

We have incurred net losses in each year since our inception and, as of December 31, 2024, we had an accumulated deficit of $3.4 billion. During the years ended December 31, 2024, 2023 and 2022, net losses attributable to ImmunityBio common stockholders were $413.6 million, $583.2 million, and $416.6 million, respectively. Substantially all of our net losses resulted principally from costs incurred in connection with our ongoing clinical trials and operations, our research and development programs, and from selling, general and administrative costs associated with our operations, including stock-based compensation expense.

As of December 31, 2024, we had 680 employees. Personnel of related companies who provide corporate, general and administrative, certain research and development, and other support services under our shared services agreement with NantWorks are not included in this number. See Note 13 *"Related-Party Agreements"* of the "Notes to Consolidated Financial Statements" that appears in Part II, Item 8. "Financial Statements and Supplementary Data" of this Annual Report for more information. In anticipation of the ongoing commercialization of our approved product, we expect to continue to incur significant expenses and increasing operating expenses for the foreseeable future, which may fluctuate significantly from quarter-to-quarter and year-to-year. See *"—Future Funding Requirements"* below for a discussion of our anticipated expenditures and sources of capital we expect to access to fund these expenditures.

Collaboration Agreements

We anticipate that strategic collaborations will continue to be an integral part of our operations, providing opportunities to leverage our partners' expertise and capabilities to gain access to new markets for our approved product and acquire new technologies or further expand the potential of our technologies, approved product and product candidates across relevant platforms. We believe we are well positioned to become a leader in immunotherapy due to our broad and vertically-integrated platforms and through complementary strategic partnerships.

We believe that our innovative approach to orchestrate and combine therapies for optimal immune system response will become a therapeutic foundation across multiple indications. Additionally, we believe that data from multiple clinical trials indicates ANKTIVA has broad potential to enhance the activity of therapeutic mAbs, including CPIs, across a wide range of tumor types and potentially rescue lymphopenia by proliferation and activation of NK and T cells. We may also enter into supply arrangements for various investigational agents to be used in our clinical trials. See Part I, Item 1. *"Business—Collaboration and License Agreements"* in this Annual Report for a more detailed discussion regarding our collaboration and license agreements.

Agreements with Related Parties

Related-Party Debt

See Note 12 *"Related-Party Debt"* of the "Notes to Consolidated Financial Statements" that appears in Part II, Item 8. "Financial Statements and Supplementary Data" of this Annual Report for more information regarding our related-party debt.

NantWorks, LLC

Our Founder, Executive Chairman and Global Chief Scientific and Medical Officer also founded and has a controlling interest in NantWorks, which is a collection of companies in the healthcare and technology space. We have entered into arrangements with NantWorks, and certain affiliates of NantWorks. Affiliates of NantWorks are also affiliates of the company due to the common control by and/or common ownership interest of our Founder, Executive Chairman and Global Chief Scientific and Medical Officer. See Note 13 *"Related-Party Agreements"* of the "Notes to Consolidated Financial Statements" that appears in Part II, Item 8. "Financial Statements and Supplementary Data" of this Annual Report for more information regarding our agreements with NantWorks.

Immuno-Oncology Clinic, Inc.

We have entered into multiple agreements with the Clinic to conduct clinical trials related to certain of our product candidates. The Clinic is a related party as it is owned by an officer of the company and NantWorks manages the administrative operations of the Clinic. See Note 13 *"Related-Party Agreements"* of the "Notes to Consolidated Financial Statements" that appears in Part II, Item 8. "Financial Statements and Supplementary Data" of this Annual Report for more information regarding our agreements with the Clinic.

Related-Party Leases

We lease property in multiple facilities across the U.S. and Italy, including facilities located in El Segundo and Culver City, CA that are leased from related parties. See Note 13 *"Related-Party Agreements"* of the "Notes to Consolidated Financial Statements" that appears in Part II, Item 8. "Financial Statements and Supplementary Data" of this Annual Report for more information about our related-party leases.

Related-Party Warrants

A total of 1,638,000 warrants issued to an affiliate of Dr. Soon-Shiong with an exercise price of $3.24 per share were outstanding as of December 31, 2024. See Note 16 *"Stock-Based Compensation"* of the "Notes to Consolidated Financial Statements" that appears in Part II, Item 8. "Financial Statements and Supplementary Data" of this Annual Report for more information regarding the related-party warrants.

Contingent Value Rights

In connection with our 2017 acquisition of Altor, we issued CVRs under which we agreed to pay the prior stockholders of Altor approximately $304.0 million of contingent consideration upon calendar-year worldwide net sales of ANKTIVA exceeding $1.0 billion prior to December 31, 2026, with amounts payable in cash or shares of our common stock or a combination thereof. As of December 31, 2024, Dr. Soon-Shiong, our Founder, Executive Chairman and Global Chief Scientific and Medical Officer, and his related party hold approximately $139.8 million of net sales CVRs. See Note 9 *"Commitments and Contingencies"* of the "Notes to Consolidated Financial Statements" that appears in Part II, Item 8. "Financial Statements and Supplementary Data" of this Annual Report for more information regarding the CVRs.

Components of our Results of Operations

Product Revenue, Net

Prior to the approval of ANKTIVA for commercial sale, we primarily generated revenues from non-exclusive license agreements related to our cell lines, the sale of our bioreactors and related consumables, and grant programs. The company expects to continue to generate revenue from these programs.

Until April 2024, we had no clinical products approved for commercial sale and thus had not generated any revenue from therapeutic and vaccine product candidates that are or were under development. Now that we have received FDA approval for ANKTIVA, we have begun to generate revenue although we expect it to take some time to generate significant revenue from our approved product and we can provide no assurance when, or if, this will occur. We began commercial distribution of our approved product in May 2024; however, we can provide no assurance with respect to our future revenues, market acceptance, reimbursement from third-party payors, or the profitability of our approved product or any other product candidate for which we may obtain approval. We do not expect additional revenue from our other product candidates unless and until we obtain regulatory approval of and commercialize any of our other product candidates, and we do not know when, or if, this will occur.

Cost of Sales

Cost of sales consists primarily of third-party manufacturing costs, distribution, and overhead costs related to ANKTIVA sales. Cost of sales may also include costs related to excess or obsolete inventory adjustment charges, abnormal costs, unabsorbed manufacturing and overhead costs, and manufacturing variances. All costs associated with the production of ANKTIVA prior to receiving regulatory approval were expensed in *research and development expense*, on the consolidated statement of operations in the period incurred and therefore are not reflected in cost of sales. We expect the cost of sales for ANKTIVA to increase in relation to product revenues as we deplete these inventories.

Operating Expenses

We generally classify our operating expenses into research and development, and selling, general and administrative expenses. Personnel costs, including salaries, benefits, bonuses, and stock-based compensation expense comprise a significant component of our research and development, and selling, general and administrative expense categories. We allocate expenses associated with our facilities and information technology costs between these two categories, primarily based on the nature of each cost.

Research and Development

Research and development expense consists of expenses incurred while performing research and development activities to discover and develop our technology and product candidates. This includes conducting preclinical studies and clinical trials, manufacturing development efforts, and activities related to regulatory submissions for our approved product and product candidates. We expense research and development costs as they are incurred.

Our research and development expenses primarily consist of:

- clinical trial and regulatory-related costs;
- expenses incurred under agreements with investigative sites and consultants that conduct our clinical trials;
- expenses incurred under collaborative agreements;

- manufacturing and testing costs and related supplies and materials;
- employee-related expenses, including salaries, benefits, travel and stock-based compensation; and
- facility expenses dedicated to research and development.

The company classifies its research and development expenses as either external or internal. The company's external research and development expenses support its various preclinical and clinical programs. The company's internal research and development expenses include payroll and benefits expenses, facilities and equipment expense, and other indirect research and development expenses incurred in support of its research and development activities. The company's external and internal resources are not directly tied to any one research or drug discovery program and are typically deployed across multiple programs and are not allocated to specific product candidates or development programs.

We expect our research and development expenses to increase significantly for the foreseeable future as we continue to invest in research and development activities related to expanding our product into new indications and markets, developing our other product candidates, and conducting our ongoing and planned clinical trials.

The process of conducting clinical trials necessary to obtain regulatory approval is costly and time consuming. The successful development of product candidates is highly uncertain. At this time, we cannot reasonably estimate the nature, timing or costs required to complete the remaining development of our other product candidates or to expand potential approved markets and indications for ANKTIVA. This is due to the numerous risks and uncertainties associated with the development of product candidates.

The costs of clinical trials may vary significantly over the life of a project owing to, but not limited to, the following:

- per patient trial costs;
- the number of sites included in the clinical trials;
- the countries in which the clinical trials are conducted;
- the length of time required to enroll eligible patients;
- the number of patients that participate in the clinical trials;
- the number of doses that patients receive;
- the cost of comparative or combination agents used in clinical trials;
- the drop-out or discontinuation rates of patients;
- potential additional safety monitoring or other studies or incremental cohorts requested by regulatory agencies;
- the duration of patient follow-up; and
- the safety profile and efficacy of the product candidate.

We have only one approved product, ANKTIVA, for which we received approval from the FDA on April 22, 2024. We began commercial distribution of our approved product in May 2024. There can be no assurance that our other product candidates will be approved for commercial sale by the FDA in the near term, if ever.

Selling, General and Administrative

Selling, general and administrative expense consists primarily of salaries and personnel-related costs, including employee benefits and any stock-based compensation, for employees performing functions other than research and development. This includes personnel in executive, finance, human resources, information technology, legal, sales and administrative support functions. Other selling, general and administrative expenses include sales and marketing costs, facility-related costs not otherwise allocated to research and development expense, professional fees for auditing, tax and legal services, advertising costs, expenses associated with strategic business transactions and business development efforts, obtaining and maintaining patents, consulting costs, royalties and licensing costs, and costs of our information systems.

We expect that our selling, general and administrative expense will increase for the foreseeable future as we commercialize our approved product and expand operations, build out information systems and increase our headcount to support continued research activities and the development of our clinical programs. We have incurred and expect that we will continue to incur in the future, additional costs associated with operating as a public company, including costs to comply with stock exchange listing and SEC requirements, future funding efforts, corporate governance, internal controls, investor relations, disclosure and similar requirements applicable to public companies. Additionally, if and when we believe that a regulatory approval of one of our other product candidates appears likely, we expect to incur significant increases in our selling, general and administrative expense relating to the sales and marketing of any additional approved product candidate.

Other Income (Expense), Net

Other income (expense), net consists primarily of interest and investment income (loss), interest expense (including amortization of debt discounts), unrealized gains and losses from investments in equity securities and equity-method investments, changes in fair value of warrant liabilities, derivative liabilities, and convertible notes, realized gains and losses on debt and equity securities, and gains and losses on foreign currency transactions.

Income Taxes

We are subject to U.S. federal income tax, as well as income tax in Italy, South Korea, California and other states. From inception through December 31, 2024, we have not been required to pay U.S. federal and state income taxes because of current and accumulated NOLs.

Discussion of Consolidated Results of Operations

Comparison of the Years Ended December 31, 2024 and 2023

	Year Ended December 31,			
	2024	2023	$ Change	% Change
	($ in thousands)			
Revenue				
Product revenue, net	$ 14,150	$ —	$ 14,150	— %
Other revenues	595	622	(27)	(4)%
Total revenue	14,745	622	14,123	2271 %
Operating costs and expenses				
Cost of sales	—	—	—	— %
Research and development (including amounts with related parties)	190,144	232,366	(42,222)	(18)%
Selling, general and administrative (including amounts with related parties)	168,783	129,620	39,163	30 %
Impairment of intangible assets	—	886	(886)	(100)%
Total operating costs and expenses	358,927	362,872	(3,945)	(1)%
Loss from operations	(344,182)	(362,250)	18,068	(5)%
Other income (expense), net:				
Interest and investment income, net	7,975	1,131	6,844	605 %
Interest expense (including amounts with related parties)	(114,670)	(128,934)	14,264	(11)%
Change in fair value of related-party convertible notes	43,472	(36,203)	79,675	(220)%
Interest expense related to revenue interest liability	(39,657)	(264)	(39,393)	14922 %
Change in fair value of warrant liabilities	19,955	(47,600)	67,555	(142)%
Change in fair value of derivative liabilities	13,477	—	13,477	— %
Loss on equity method investment	—	(7,549)	7,549	(100)%
Other expense, net (including amounts with related parties)	(15)	(2,223)	2,208	(99)%
Total other income (expense), net	(69,463)	(221,642)	152,179	(69)%
Loss before income taxes and noncontrolling interests	(413,645)	(583,892)	170,247	(29)%
Income tax benefit	—	40	(40)	(100)%
Net loss	$ (413,645)	$ (583,852)	$ 170,207	(29)%

Product Revenue, Net

Product revenue, net increased $14.1 million during the year ended December 31, 2024, as compared to the year ended December 31, 2023. The increase was driven by sales of ANKTIVA after FDA approval in April 2024.

Other Revenues

Other revenues are consistent during the year ended December 31, 2024, as compared to the year ended December 31, 2023.

Cost of Sales

We did not report cost of sales during the years ended December 31, 2024 and 2023. Cost of sales consists primarily of third-party manufacturing, distribution and overhead costs. All costs associated with the production of ANKTIVA prior to receiving regulatory approval were expensed in *research and development expense*, on the consolidated statement of operations in the period incurred and therefore are not reflected in cost of sales. As a result, our initial product gross margin is higher as our pre-launch inventory costs are not included in the cost of sales. We expect the cost of sales for ANKTIVA to increase in relation to product revenues as we deplete these inventories.

Research and Development Expense

Research and development expense decreased $42.2 million during the year ended December 31, 2024, as compared to the year ended December 31, 2023. The following table summarizes our research and development expenses during the years ended December 31, 2024 and 2023, together with the changes in those items (in thousands):

	Year Ended December 31,		
	2024	2023	$ Change
External research and development expenses	$ 29,268	$ 67,124	$ (37,856)
Internal research and development expenses:			
Personnel-related costs	90,864	89,085	1,779
Equipment, depreciation, and facility costs	52,176	51,810	366
Other research and development costs	17,836	24,347	(6,511)
Total internal research and development expenses	160,876	165,242	(4,366)
Total research and development expense	$ 190,144	$ 232,366	$ (42,222)

Research and development expense decreased $42.2 million primarily attributable to the following:

- a $37.9 million decrease in external research and development expenses that was primarily due to a reduction in CMO fees and testing services, a reduction in clinical trial costs, and a reduction in outside service costs;
- a $1.8 million increase in personnel-related costs that was primarily due to an increase in salary and benefits expenses from the expansion of the regulatory and sales teams during the year ended December 31, 2024, a reversal in 2023 of the 2022 accrued discretionary bonuses and a reduction in headcount during the year ended December 31, 2023, partially offset by an increase in shared service costs charged out and a decrease in stock-based compensation costs due to the prior years' retention awards fully vesting during the year ended December 31, 2024;
- a $0.4 million increase in equipment, depreciation, and facility costs that was primarily due to increases in software purchases, facility expenses and common area maintenance costs, partially offset by decreases in depreciation and amortization expenses and lease expenses; and
- a $6.5 million decrease in other research and development costs, primarily attributable to lower material supply costs due to decreased production activities, a reclass of overhead costs to capitalized inventory and lower research agreement expenses, partially offset by an increase from no costs allocated to a joint venture and an increase in drug costs.

We expect our research and development expenses to increase significantly for the foreseeable future as we continue to invest in research and development activities related to developing our product candidates and conduct our ongoing and planned clinical trials.

Selling, General and Administrative Expense

Selling, general and administrative expense increased $39.2 million during the year ended December 31, 2024, as compared to the year ended December 31, 2023. The rise in expenses was primarily due to a $19.8 million increase in legal expenses driven by higher defense and settlement costs and increased general legal services, a $14.6 million increase in consulting fees primarily associated with commercial readiness activities, an $8.3 million increase in salary and benefits primarily from the reversal in 2023 of the 2022 accrued discretionary bonuses, and a reduction in headcount during the year ended December 31, 2023, a $2.2 million increase in other operating costs due to post commercialization marketing activities, a $1.3 million increase in license fees, a $1.1 million increase in audit and tax fees, a $0.9 million increase in recruiting and training costs and a $0.4 million increase in travel expenses, partially offset by a $9.4 million decrease in stock-based compensation expense.

Impairment of Intangible Assets

Impairment of intangible assets decreased $0.9 million during the year ended December 31, 2024 as compared to the year ended December 31, 2023. The $0.9 million impairment charge during the year ended December 31, 2023 was related to indefinite-lived intangible assets associated with the Tarmogen platform as the research and development program was limited. There was no impairment of intangible assets incurred during the year ended December 31, 2024.

Other Income (Expense), Net

Other income (expense), net decreased $152.2 million during the year ended December 31, 2024, as compared to the year ended December 31, 2023. The reduction in other income (expense), net was primarily due to a change of $79.7 million in fair value of convertible notes driven by the revaluation gain of $43.5 million during the year ended December 31, 2024, as compared to the $36.2 million loss during the year ended December 31, 2023, a change of $67.6 million due to the reduction of fair value of warrant liabilities, a decrease of $14.3 million in interest expense (including amounts with related parties), a change of $13.5 million in the fair value of derivative liabilities, a decrease of $7.5 million due to loss on equity method investments recorded during the year ended December 31, 2023, an increase of $6.8 million in interest and investment income, net and a decrease of $2.2 million in other income (expense), net (including amounts with related parties), partially offset by an increase of $39.4 million in interest expense related to the revenue interest liability.

Comparison of the Years Ended December 31, 2023 to 2022

See Part II, Item 7. *"Management's Discussion and Analysis of Financial Condition and Results of Operations—Results of Operations"* of our Annual Report filed with the SEC on March 19, 2024 for a discussion of the company's results of operations during the year ended December 31, 2023 compared to the year ended December 31, 2022.

Financial Condition, Liquidity and Capital Resources

Sources of Liquidity

From inception through December 31, 2024, we have funded our operations primarily through proceeds from the issuance of related-party promissory notes, sales of common stock under our shelf registration statements and through RDOs, and a RIPA financing.

Cash and Marketable Securities on Hand

As of December 31, 2024, we had cash and cash equivalents, and marketable securities of $149.8 million compared to $267.4 million as of December 31, 2023. We have typically invested our cash in a variety of financial instruments and classified these investments as available-for-sale. However, after our entry into the RIPA we can no longer invest our excess funds in corporate or European bonds. Certain of our investments are subject to credit, liquidity, market, and interest-rate risks. The general condition of the financial markets and the economy may increase those risks and may affect the value and liquidity of investments and restrict our ability to access the capital markets.

Shelf Registration Statements

During 2023, we filed a $750.0 million shelf registration statement with the SEC on Form S-3 for the offering and sale of equity and equity-linked securities, including common stock, preferred stock, debt securities, depositary shares, warrants to purchase common stock, preferred stock or debt securities, subscription rights, purchase contracts, and units. As of December 31, 2024, we had $565.6 million available for use under this shelf.

In April 2024, we filed a shelf registration statement with the SEC on Form S-3ASR pursuant to which we may, from time to time, sell an indeterminate amount of our common stock, preferred stock, debt securities, depositary shares, warrants, subscription rights, purchase contracts, or units, and an associated prospectus related to the ATM.

Exercise of Warrants

Pursuant to warrant agreements issued in connection with our RDOs, we issued warrants to institutional holders. During the year ended December 31, 2024, institutional holders exercised a total of 22,242,740 warrants pursuant to the warrant agreements at an exercise price of $3.2946 per share resulting in the issuance of 22,242,740 shares of the company's common stock for proceeds totaling $73.3 million. As of December 31, 2024, a total of 6,399,171 warrants remain outstanding with an exercise price of $3.2946 per share and an expiration date of July 24, 2026.

Revenue Interest Purchase Agreement

On December 29, 2023, we entered into the RIPA with Infinity and Oberland. Pursuant to the RIPA, Oberland had the option to purchase additional Revenue Interests from us in exchange for a $100.0 million Second Payment upon satisfaction of certain conditions in the RIPA, including receipt of approval from the FDA of our BLA for ANKTIVA on or before June 30, 2024. On April 22, 2024, the FDA approved our product ANKTIVA and as a result, on May 13, 2024 Oberland purchased additional Revenue Interests from us for a gross purchase price of $100.0 million, less certain issuance costs.

As consideration for the aforementioned payments, Oberland has the right to receive quarterly Revenue Interest Payments from us based on, among other things, a certain percentage of our net sales during such quarter, which are tiered payments ranging from 4.5% to 10.0% (before funding of the Second Payment, 3.0% to 7.0%) of the company's worldwide net sales, excluding those in China. See Note 11 *"Revenue Interest Purchase Agreement"* of the "Notes to Consolidated Financial Statements" that appears in Part II, Item 8. "Financial Statements and Supplementary Data" of this Annual Report for more information regarding our payment obligations under the RIPA.

Conversion of Related-Party Promissory Notes

On December 10, 2024 in connection with an equity offering, the company received written notices from Nant Capital, the holder of the $30.0 million promissory note due December 31, 2025 and the $200.0 million promissory note due September 11, 2026, of its election to convert the entire outstanding principal and accrued interest due under the existing notes into shares of the company's common stock. As of such date, the total outstanding principal and accrued and unpaid interest due under the existing notes of approximately $30.7 million was converted into 13,475,172 shares of the company's common stock at a price of $2.28 per share (for the $30.0 million note) and approximately $200.7 million was converted into 103,710,088 shares of the company's common stock at a price of $1.9350 per share (for the $200.0 million note) in accordance with the terms of the existing promissory notes.

See Note 12 *"Related-Party Debt"* of the "Notes to Consolidated Financial Statements" that appears in Part II, Item 8. "Financial Statements and Supplementary Data" of this Annual Report for more information regarding our related-party debt.

Stock Purchase and Option Agreement

On December 29, 2023 and in connection with the RIPA, we entered into an SPOA with Oberland. Under this agreement, Oberland had an option to purchase up to $10.0 million of our common stock, at a price per share to be determined by reference to the 30-day trailing volume weighted-average price of our common stock, calculated from the date of exercise. The option is exercisable by Oberland at any time until the earliest of (i) December 29, 2028, (ii) a change of control of the company, or (iii) a sale of substantially all of the company's assets. Among other limitations, the option may only be exercised to the extent that the common stock issuable pursuant to such exercise would not exceed 19.9% of the common stock outstanding immediately after giving effect to such exercise.

Pursuant to the SPOA, in April 2024 Oberland exercised its option to purchase 858,990 shares of our common stock at an exercise price of $5.8208 per share generating net proceeds of approximately $4.9 million. In relation to this transaction, we recorded $7.6 million in *additional paid-in capital,* on the statement of stockholders' deficit during the year ended December 31, 2024. Following such exercise, approximately $5.0 million remains available for future exercise under the SPOA as of December 31, 2024.

Uses of Liquidity

In addition to the cash used to fund our operating activities discussed in "*—Future Funding Requirements*" below, we will require cash to settle the following obligations:

- As of December 31, 2024, our indebtedness payable at maturity is $505.0 million. This convertible promissory note is held by Nant Capital, an entity affiliated with Dr. Soon-Shiong. In connection with the RIPA, our related-party promissory note is a general unsecured obligation of the company that is subordinated in right of payment to indebtedness, obligations, and other liabilities under the RIPA, the Revenue Interests issued pursuant to such agreement, and refinancing of the foregoing.

  There can be no assurance that the company can refinance this promissory note or what terms will be available in the market at the time of refinancing. Furthermore, if prevailing interest rates or other factors at the time of refinancing result in higher interest rates upon refinancing, then the interest expense relating to the refinanced indebtedness would increase. These risks could materially adversely affect the company's financial condition, cash flows and results of operations.

- On December 29, 2023, we entered into the RIPA with Infinity and Oberland. Oberland has the right to receive quarterly Revenue Interest Payments from us based on, among other things, our worldwide net sales, excluding those in China, which will be tiered payments initially ranging from 4.5% to 10.0% (before funding of the Second Payment, 3.0% to 7.0%), subject to increase or decrease, following December 31, 2029 (the Test Date) depending on whether our aggregate payments made to Oberland as of the Test Date have met or exceeded the Cumulative Purchaser Payments. In addition, if our aggregate payments made as of the Test Date to Oberland do not equal or exceed the amount of the Cumulative Purchaser Payments as of such date, then we are obligated to make a one-time True-Up Payment to Oberland in an amount equal to 100% of the Cumulative Purchaser Payments as of the Test Date, less the aggregate amount of our previous payments to Oberland as of the Test Date. See Note 11 *"Revenue Interest Purchase Agreement"* of the "Notes to Consolidated Financial Statements" that appears in Part II, Item 8. "Financial Statements and Supplementary Data" of this Annual Report for more information regarding the RIPA.

- In connection with our 2017 acquisition of Altor, we issued CVRs under which we agreed to pay the prior stockholders of Altor approximately $304.0 million of contingent consideration upon calendar-year worldwide net sales of ANKTIVA exceeding $1.0 billion prior to December 31, 2026, with amounts payable in cash or shares of our common stock or a combination thereof. As of December 31, 2024, Dr. Soon-Shiong and his related party hold approximately $139.8 million of net sales CVRs and they have both irrevocably agreed to receive shares of the company's common stock in satisfaction of their CVRs. We may be required to pay the other prior Altor stockholders up to $164.2 million for their net sales CVRs should they choose to have their CVRs paid in cash instead of common stock. We may need to seek additional sources of capital to satisfy the CVR obligations if they are achieved.

- In connection with our acquisition of VivaBioCell, we are obligated to pay the former owners approximately $2.1 million of contingent consideration upon the achievement of a regulatory milestone relating to the GMP-in-a-Box technology.

Discussion of Consolidated Cash Flows

The following discussion of ImmunityBio's cash flows is based on the consolidated statements of cash flows in Part II, Item 8. "Financial Statements and Supplementary Data" and is not meant to be an all-inclusive discussion of the changes in its cash flows for the years presented below.

The following table sets forth our primary sources and uses of cash for the years indicated (in thousands):

	Year Ended December 31,	
	2024	2023
Cash (used in) provided by:		
Operating activities	$ (391,236)	$ (366,757)
Investing activities	(12,246)	(30,470)
Financing activities	281,630	558,341
Effects of exchange rate changes on cash and cash equivalents, and restricted cash	(23)	(292)
Net change in cash and cash equivalents, and restricted cash	$ (121,875)	$ 160,822

Operating Activities

During the year ended December 31, 2024, net cash used in operating activities of $391.2 million consisted of a net loss of $413.6 million and $19.4 million of cash used in net working capital, partially offset by $41.8 million in adjustments for non-cash items. The changes in net working capital consisted primarily of an increase of $8.3 million in inventories, a decrease of $5.5 million in operating lease liabilities, a decrease of $3.2 million in accounts payable, an increase of $2.4 million in accounts receivable, net, a decrease of $1.4 million in accrued expenses, and an increase of $1.1 million in other assets, partially offset by a decrease of $1.7 million in prepaid expenses and other current assets and an increase of $0.8 million with related parties. Adjustments for non-cash items primarily consisted of $38.0 million of non-cash interest expense related to the revenue interest liability, $34.4 million in stock-based compensation expense, $22.6 million in amortization of related-party note discounts, $17.6 million in depreciation and amortization expense, $5.8 million in non-cash lease expense related to operating lease right-of-use assets, $1.2 million in non-cash interest primarily related to related-party promissory notes, $0.6 million in unrealized losses on equity securities driven by a decrease in the value of our investments, and $0.1 million in other items, reduced by a $43.5 million change in the fair value of a related-party convertible note, a $20.0 million change in fair value of warrant liabilities, a $13.5 million change in the fair value of derivative liabilities, and $1.5 million of accretion of discounts on marketable debt securities.

During the year ended December 31, 2023, net cash used in operating activities of $366.8 million consisted of a net loss of $583.9 million, partially offset by $213.1 million in adjustments for non-cash items and $4.0 million of cash provided by net working capital. Adjustments for non-cash items primarily consisted of $49.2 million in stock-based compensation expense, $47.6 million in change in fair value of warrant liabilities, $42.4 million in amortization of debt issuance costs and accretion of discounts, $36.2 million in change in fair value of convertible notes, $18.5 million in depreciation and amortization expense, $8.9 million in non-cash interest primarily related to related-party promissory notes, $6.1 million in non-cash lease expense related to operating lease right-of-use assets, $2.0 million of transaction costs allocable to warrant liabilities, $1.6 million in unrealized losses on equity securities driven by a decrease in the value of our investments, $0.9 million in loss on impairment of intangible assets, and $0.3 million of non-cash interest expense related to the revenue interest liability, partially offset by $0.5 million in other items and a decrease of $0.1 million in amortization of premiums, net of discounts on marketable debt securities. The changes in net working capital consisted primarily of an increase of $6.7 million in accrued expenses, a decrease of $6.0 million in prepaid expenses and other current assets, and a decrease of $1.9 million in other assets, partially offset by a decrease of $6.5 million in accounts payable, a decrease of $3.0 million in operating lease liabilities, and a decrease of $1.1 million in due to related parties.

We have historically experienced negative cash flows from operating activities, with such negative cash flows likely to continue for the foreseeable future.

Investing Activities

During the year ended December 31, 2024, net cash used in investing activities was $12.2 million, which included cash outflows of $140.2 million for purchases of marketable debt securities, $6.9 million in purchases of property, plant and equipment, $1.0 million used for the acquisition of a business, net of transaction costs, and $0.7 million cash paid for other investments, partially offset by proceeds of $136.6 million from maturities and sales of marketable debt and equity securities.

During the year ended December 31, 2023, net cash used in investing activities was $30.5 million, which included cash outflows of $30.6 million in purchases of property, plant and equipment (including construction in progress and the completion of a warehouse facility), and $10.4 million in purchases of marketable debt securities, partially offset by cash inflows of $10.5 million from maturities and sales of marketable debt and equity securities.

Our investments in property, plant and equipment are primarily related to acquisitions of equipment that will be used for the manufacturing of our approved product and product candidates and expenditures related to the buildout of our manufacturing facilities. We expect to accelerate our capital spending as we scale our GMP manufacturing capabilities, which will require significant capital for the foreseeable future.

Financing Activities

During the year ended December 31, 2024, net cash provided by financing activities was $281.6 million, which consisted of $111.4 million in net proceeds from equity offerings, $97.0 million in net proceeds from payments received pursuant to the RIPA, $73.3 million of proceeds from the exercise of warrants, $4.9 million in net proceeds from the partial exercise of the Oberland stock option, and $0.7 million in proceeds from the exercise of stock options, partially offset by $5.6 million related to net share settlement of vested RSUs for payment of payroll tax withholding and $0.1 million in principal payments of finance leases.

During the year ended December 31, 2023, net cash provided by financing activities was $558.3 million, which consisted of $258.7 million in net proceeds from issuances of related-party promissory notes, $192.8 million in net proceeds from payments received pursuant to the RIPA, $100.5 million in net proceeds from equity offerings, $9.5 million in net proceeds from issuance of common stock in connection with the RIPA, and $0.3 million in proceeds from the exercise of stock options, partially offset by $3.4 million related to net share settlement of vested RSUs for payment of payroll tax withholding, and $0.1 million used for principal payments of finance leases.

Comparison of the Years Ended December 31, 2023 to 2022

See Part II, Item 7. *"Management's Discussion and Analysis of Financial Condition and Results of Operations—Results of Operations"* of our Annual Report filed with the SEC on March 19, 2024 for a discussion of the company's consolidated cash flows for the year ended December 31, 2023 compared to the year ended December 31, 2022.

Future Funding Requirements

Prior to the approval of ANKTIVA for commercial sale, we primarily generated revenues from non-exclusive license agreements related to our cell lines, the sale of our bioreactors and related consumables, and grant programs. The company expects to continue to generate revenue from these programs.

Until April 2024, we had no clinical products approved for commercial sale and thus had not generated any revenue from therapeutic and vaccine product candidates that are or were under development. Now that we have received FDA approval for ANKTIVA, we have begun to generate revenue although we expect it to take some time to generate significant revenue from our approved product and we can provide no assurance when, or if, this will occur. We began commercial distribution of our approved product in May 2024; however, we can provide no assurance with respect to our future revenues, market acceptance, reimbursement from third-party payors, or the profitability of our approved product or any other product candidate for which we may obtain approval. We do not expect additional revenue from our other product candidates unless and until we obtain regulatory approval of and commercialize any of our other product candidates, and we do not know when, or if, this will occur. In addition, we expect our operating expenses to significantly increase in connection with our ongoing development activities,

particularly as we continue the research, development and clinical trials of, and seek regulatory approval for, our other product candidates. We have also incurred and expect that we will continue to incur in the future additional costs associated with operating as a public company as well as costs related to future fundraising efforts. In addition, subject to obtaining regulatory approval of our other product candidates, we expect to incur significant incremental commercialization expenses for product sales, marketing, manufacturing and distribution. We anticipate that we will need substantial additional funding in connection with our continuing operations.

We expect that our operating expenses will increase substantially if and as we:

- commercialize our approved product;
- continue research and development, including preclinical and clinical development of our other existing product candidates;
- seek regulatory approval of our approved product in incremental markets and indications and potentially seek regulatory approval for our other product candidates;
- seek to discover and develop additional product candidates;
- establish a commercialization infrastructure and scale up our manufacturing and distribution capabilities to commercialize any of our other product candidates for which we may obtain regulatory approval;
- seek to comply with regulatory standards and laws;
- maintain, leverage and expand our intellectual property portfolio;
- hire clinical, manufacturing, scientific and other personnel to support our product candidates' development and future commercialization efforts;
- add operational, financial and management information systems and personnel; and
- incur additional legal, accounting and other expenses in operating as a public company.

As a result of continuing anticipated operating cash outflows as we commercialize our approved product and accelerate our development efforts, we believe that substantial doubt exists regarding our ability to continue as a going concern without additional funding or financial support. However, we believe our existing cash and cash equivalents, and investments in marketable securities; sales of our approved product; capital to be raised through equity offerings, including but not limited to, the offering, issuance and sale by us of our common stock under the February 2023 shelf registration statement, of which we had $565.6 million available for future offerings as of December 31, 2024; and our potential ability to borrow from affiliated entities will be sufficient to fund our operations through at least the next 12 months following the issuance date of the consolidated financial statements based primarily upon our Founder, Executive Chairman and Global Chief Scientific and Medical Officer's intent and ability to support our operations with additional funds, including loans from affiliated entities, as required, which we believe alleviates such doubt. In addition to funds from the future sales of our approved product, which we expect to take time to establish, we may also seek to sell additional equity, through one or more follow-on public offerings, or in separate financings, or obtain a credit facility, issue other debt in compliance with the terms of the RIPA, or engage in strategic partnership transactions. However, we may not be able to secure such external financing in a timely manner or on favorable terms, if at all. Without additional funds, we may choose to delay or reduce our operating or investment expenditures. Further, because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, we may need additional funds to meet our needs sooner than planned.

We will need to obtain additional financing to fund our future operations, including completing the commercialization of our approved product and the development and commercialization of our other product candidates. Changing circumstances may cause us to increase our spending significantly faster than we currently anticipate and we may need to raise additional funds sooner than we presently anticipate. Moreover, research and development and our operating costs and fixed expenses such as rent and other contractual commitments, including those for our research collaborations, are substantial and are expected to increase in the future.

Our future funding requirements will depend on many factors, including, but not limited to:

- our ability and the time required to successfully commercialize our approved product;
- progress, timing, number, scope and costs of researching and developing our product candidates and our ongoing, planned and potential clinical trials;
- time and cost of regulatory approvals;
- our ability to successfully commercialize any of our other product candidates, if approved and the costs of such commercialization activities;
- revenue from product candidates that we may commercialize, if any, including the selling prices for such potential products and the availability of adequate third-party coverage and reimbursement for patients;
- interest and principal payments on our related-party promissory note, and repayment of Revenue Interests and Test Date payments due under the RIPA;
- cost of building, staffing and validating our own manufacturing facilities in the U.S., including having a product candidate successfully manufactured consistent with FDA and EMA regulations;
- terms, timing and costs of our current and any potential future collaborations, business or product acquisitions, CVRs, milestones, royalties, licensing or other arrangements that we have established or may establish;
- time and cost necessary to respond to technological, regulatory, political and market developments; and
- costs of filing, prosecuting, maintaining, defending and enforcing any patent claims and other intellectual property rights.

Unless and until we can generate a sufficient amount of revenues, we may finance future cash needs through public or private equity offerings, license agreements, debt financings, collaborations, strategic alliances and marketing or distribution arrangements. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms, or at all.

To the extent that we raise additional capital through the sale of equity or equity-linked securities (including warrants), convertible debt or through our shelf registration statements, or other offerings, or if any of our current debt is converted into equity or if our existing warrants are exercised, 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 additional indebtedness would result in increased fixed payment obligations and could involve certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. If we raise additional funds through strategic partnerships and alliances and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or product candidates, or grant licenses on terms unfavorable to us and our revenue interest liability may come due. We have no committed source of additional capital and if we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may be required to delay or reduce the scope of or eliminate one or more of our research or development programs or our commercialization efforts. Our current license and collaboration agreements may also be terminated if we are unable to meet the payment obligations under those agreements. As a result, we may seek to access the public or private capital markets whenever conditions are favorable, even if we do not have an immediate need for additional capital at that time.

Contractual Obligations

We have material cash requirements to pay related-party affiliates and third parties under various contractual obligations discussed below:

- We are obligated to make payments to several related-party affiliates under written agreements and other informal arrangements. We are also obligated to pay interest and to repay principal under our related-party promissory note. See Note 12 *"Related-Party Debt"* of the "Notes to Consolidated Financial Statements" that appears in Part II, Item 8. "Financial Statements and Supplementary Data" of this Annual Report for information regarding our financing obligations.

- We are obligated to make payments to Oberland associated with our revenue interest liability, which do not have a fixed repayment schedule. Oberland's right to receive payments under the RIPA shall terminate when Oberland has received maximum payments (including any True-Up Payment) equal to 195.0% of the then Cumulative Purchaser Payments unless the RIPA is terminated prior to such date.

  Under the terms of the agreement, prior to the Test Date, every $100.0 million of worldwide net sales, excluding those in China, of less than or equal to $600.0 million in a calendar year will result in a tiered Revenue Interest Payment of approximately $10.0 million or 10.0% (after funding of the Second Payment). Worldwide net sales, excluding those in China, for a calendar year exceeding $600.0 million will result in a tiered Revenue Interest Payment of approximately $4.5 million or 4.5% (after funding of the Second Payment) for every $100.0 million of worldwide net sales, excluding those in China, above the threshold.

  In the future, cumulative worldwide net sales, excluding those in China, levels up to the Test Date will determine whether or not we are required to make a True-Up Payment and implement modified payment rates. The amount of the obligation and timing of payment is likely to change. See Note 11 *"Revenue Interest Purchase Agreement"* of the "Notes to Consolidated Financial Statements" that appears in Part II, Item 8. "Financial Statements and Supplementary Data" of this Annual Report for more information regarding the RIPA.

- We are obligated to make payments under our operating leases, which primarily consist of facility leases. See Note 10 *"Lease Arrangements"* and Note 13 *"Related-Party Agreements"* of the "Notes to Consolidated Financial Statements" that appear in Part II, Item 8. "Financial Statements and Supplementary Data" of this Annual Report for information regarding our lease obligations.

- In connection with the acquisitions of Altor and VivaBioCell, we are obligated to pay contingent consideration upon the achievement of certain milestones. See Note 9 *"Commitments and Contingencies—Contingent Consideration Related to Business Combinations"* of the "Notes to Consolidated Financial Statements" that appears in Part II, Item 8. "Financial Statements and Supplementary Data" of this Annual Report for information regarding our contingent consideration obligations.

- We have certain contractual commitments to make payments to related-party affiliates and third parties that are expected to be paid during the following periods:

  - Fiscal Year 2025 – $37.0 million is estimated to be payable, primarily related to capital expenditures and open purchase orders as of December 31, 2024 for the acquisition of goods and services in the ordinary course of business, and near-term upfront milestone payments to third parties. The timing of payment depends on the actual progress of buildouts, completion of services, and the realization of milestones associated with third-party agreements; and

  - Fiscal year 2026 and beyond – Up to a maximum of $387.8 million as of December 31, 2024 based on the achievement of various development, regulatory and commercial milestones for agreements with third parties. These payments may not be realized or may be modified and are contingent upon the occurrence of various future events, substantially all of which have a high degree of uncertainty of occurring.

  See Note 9 *"Commitments and Contingencies—Unconditional Purchase Obligations"* of the "Notes to Consolidated Financial Statements" that appears in Part II, Item 8. "Financial Statements and Supplementary Data" of this Annual Report for information on these unconditional purchase obligations.

- In connection with our leasehold interest in the Dunkirk Facility, we committed to spend an aggregate of $1.52 billion on operational expenses during the initial 10-year term, and an additional $1.50 billion on operational expenses if we elect to renew the lease for the additional 10-year term. These amounts are not included in the discussion above. See Note 8 *"Collaboration and License Agreements and Acquisition—Acquisition"* of the "Notes to Consolidated Financial Statements" that appears in Part II, Item 8. "Financial Statements and Supplementary Data" of this Annual Report for more information on these obligations.

Critical Accounting Policies and Estimates

Our discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of consolidated financial statements requires management to make certain estimates and assumptions that affect the reported amounts of assets, liabilities and expenses and the disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. Those estimates can be complex and actual results could differ materially from those estimates. Estimates are assessed each period and updated to reflect current information.

While our significant accounting policies are more fully described in the notes accompanying our consolidated financial statements that appear in Part II, Item 8. "Financial Statements and Supplementary Data" of this Annual Report, we believe the following accounting policies to be the most critical in understanding the judgments and estimates we use in preparing our consolidated financial statements:

Revenue Recognition

Product Revenue, Net

After FDA approval in April 2024, the company began recognizing revenue from the sale of ANKTIVA in accordance with FASB ASC Topic 606, *Revenue from Contracts with Customers* (ASC 606). The provisions of ASC 606 require the following steps to determine revenue recognition: (i) identification of contract with the customers; (ii) identification of performance obligations; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations based on estimated selling prices; and (v) recognition of revenue when (or as) we satisfy each performance obligation. At contract inception, we assess the goods or services promised within each contract, determine whether each promised good or service is distinct and identify those that are performance obligations. We recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

The company entered into a third-party logistics agreement to engage a 3PL Agent to distribute the company's products to its customers. The 3PL Agent provides services to the company that include storage, shipping and distribution, processing product returns, as well as customer service, order to cash, and logistics support. The company's customers are currently limited to pharmaceutical specialty distributors and specialty pharmacy. The company primarily sells ANKTIVA to specialty distributors through a drop-ship arrangement under which orders from various healthcare institutions such as hospitals, medical facilities, physician practices, pharmacies and government agencies are processed through and controlled by specialty distributors. Under the drop-ship arrangement, the 3PL Agent ships the product to various health care institutions without the specialty distributor ever taking physical possession of the product. The company recognizes product revenue when ANKTIVA is delivered to the destination as instructed and controlled by specialty distributors.

The company also sells ANKTIVA directly to a specialty pharmacy who then subsequently distributes ANKTIVA to physicians, clinics, and certain medical centers, hospitals or other healthcare institutions. The company recognizes product revenue when ANKTIVA is delivered to the specialty pharmacy location.

Product revenue is recorded with each sale at wholesale acquisition cost, net of: (a) consideration payable to customers; and (b) variable considerations. The company pays fees to the specialty distributors for certain administrative services associated with the distribution of the product wherein the terms of which are also detailed in its contracts. Such fees are not for a distinct good or service and, accordingly, are recorded as a reduction of revenue, as well as a reduction of accounts receivable (trade discounts) or as a component of accrued expenses (distributor fees). The variable consideration components include, but are not limited to, prompt payment discounts, product returns, chargebacks, rebates, and co-payment assistance, which are collectively referred to as "Gross-to-Net Adjustments." In accordance with ASC 606, the company must make significant judgments to determine the estimates for certain variable considerations. Variable consideration is included in the transaction price only to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved. The company utilizes the expected value method when estimating the amount of variable consideration to include in the transaction price with respect to each of the foregoing variable consideration components. Where appropriate, these estimates are based on factors such as industry and forecasted customer buying and payment patterns, our experience, current contractual and statutory requirements, and specific known market events and trends.

Variable considerations are reassessed each reporting period, and adjustments are recorded on a cumulative catch-up basis, which affects product revenue and net income in the period of adjustment. The actual amounts of variable consideration ultimately received may differ from our estimates. If actual results in future periods vary from our estimates, we adjust these estimates accordingly. As we gain more experience, estimates will be more heavily based on the expected utilization from historical data we have accumulated since the ANKTIVA product launch. The consideration payable to customers and contingent considerations reflect our best estimates of the amount of consideration to which we are entitled based on the terms of the contracts.

Other Revenues

Prior to the approval of ANKTIVA for commercial sale, we primarily generated revenues from non-exclusive license agreements related to our cell lines, the sale of our bioreactors and related consumables, and grant programs. The company expects to continue to generate revenue from these programs.

We sell our proprietary GMP-in-a-Box bioreactors and related consumables to affiliated companies and third parties. The arrangements typically include delivery of bioreactors, consumables, and providing installation service and perpetual software licenses for using the equipment. We recognize revenue when customers obtain control and can benefit from the promised goods or services, generally upon installation of the bioreactors, in an amount that reflects the consideration that we expect to receive in exchange for those goods or services. Upfront payments and fees are recorded as deferred revenue upon receipt and recognized as revenue when we satisfy our performance obligations under these arrangements.

Grant revenue is typically paid for reimbursable costs incurred over the duration of the associated research project or clinical trial and is recognized either when expenses reimbursable under the grants have been incurred and payments under the grants become contractually due or when cash is received, depending on the certainty of payment and other factors specific to each grant.

License Agreements with Third Parties

The company has nonexclusive license agreements with a limited number of pharmaceutical and biotechnology companies that grant them the right to use our cell lines and intellectual property for non-clinical use. These agreements generally include upfront fees and annual research license fees for such use, as well as commercial license fees for sales of the licensee products developed or manufactured using our intellectual property and cell lines.

Under our license agreements with customers, we typically promise to provide a license to use certain cell lines and related patents, the related know-how, and future research and development data that affect the license. We have concluded that these promises represent a single performance obligation due to the highly interrelated nature of the promises. We provide the cell lines and know-how immediately upon entering into the contracts. Research and development data are provided throughout the term of the contract when and if available. A performance obligation is a promise in a contract to transfer a distinct good or service to the customer. A contract's transaction price is allocated to each distinct performance obligation based on relative standalone selling price and recognized as revenue when, or as, the performance obligation is satisfied.

Our license agreements may include non-refundable upfront payments, event-based milestone payments, sales-based royalty payments, or some combination of these. The event-based milestone payments represent variable consideration, and we use the most likely amount method to estimate this variable consideration. Given the high degree of uncertainty around the achievement of these milestones, we do not recognize revenue from these milestone payments until the uncertainty associated with these payments is resolved. We currently estimate variable consideration related to milestone payments to be zero and, as such, no revenue has been recognized for milestone payments. We recognize revenue from sales-based royalty payments when or as sales occur. On a quarterly basis, we re-evaluate our estimate of milestone variable consideration to determine whether any amount should be included in the transaction price and recorded in revenue prospectively.

Inventories

Inventory is stated at the lower of cost or net realizable value and consists of raw materials, work-in-progress and finished goods. Cost is determined using a standard cost method, which approximates actual cost, and assumes a FIFO flow of goods. Inventory that is used for clinical development purposes is expensed in *research and development expense*, on the consolidated statement of operations when consumed.

Cost of sales consists primarily of third-party manufacturing costs, distribution, and overhead costs related to sales of approved product subsequent to receiving regulatory approval. Cost of sales may also include costs related to excess or obsolete inventory adjustment charges, abnormal costs, unabsorbed manufacturing and overhead costs, and manufacturing variances. All costs associated with the production of ANKTIVA prior to receiving regulatory approval were expensed in *research and development expense*, on the consolidated statement of operations in the period incurred and therefore are not reflected in cost of sales.

The work-in-progress materials consists of bulk drug substance and drug product, which have a multi-year shelf life. When the bulk drug substance is manufactured into ANKTIVA drug product, those goods have a shelf life of two years from the date of manufacture. During September 2024, the shelf life of ANKTIVA drug product was extended to three years. The work-in-progress drug product gets converted to finished goods at the time of labeling. Our expectation is to sell finished goods at least twelve months prior to expiration. Due to our long manufacturing lead time, it was necessary to build up inventory in support of ANKTIVA forecasted sales. As a result of being in the early stages of the ANKTIVA product launch, the company is continuing to evaluate the length of its operating cycle.

On a quarterly basis, the company analyzes its inventory levels for excess quantities and obsolescence (expiration), taking into account factors such as historical and anticipated future sales compared to quantities on hand and the remaining shelf life. As of December 31, 2024, we determined that a reserve related to ANKTIVA inventory for excess quantities and obsolescence was not required. In addition, since the FDA approval of ANKTIVA the company has not recorded any inventory write downs.

Revenue Interest Liability

On December 29, 2023, we entered into the RIPA with Infinity and Oberland. Pursuant to the RIPA, Oberland acquired certain Revenue Interests from us for a gross purchase price of $200.0 million paid on closing. In addition, Oberland may purchase additional Revenue Interests from us in exchange for the $100.0 million Second Payment upon satisfaction of certain conditions specified in the RIPA. Under the RIPA, Oberland has the right to receive quarterly payments from us based on, among other things, a certain percentage of our worldwide net sales, excluding those in China, during such quarter. The RIPA is considered a sale of future revenues and is accounted for as a liability net of a debt discount comprised of deferred issuance costs, the fair value of a freestanding option agreement related to the SPOA, and the fair value of embedded derivatives requiring bifurcation on the consolidated balance sheet. The company imputes interest expense associated with this liability using the effective interest rate method. The effective interest rate is calculated based on the rate that would enable the debt to be repaid in full over the anticipated life of the arrangement. Interest expense is recognized over the estimated term on the consolidated statement of operations. The interest rate on this liability may vary during the term of the agreement depending on a number of factors, including the level of actual and forecasted net sales. The company evaluates the interest rate quarterly based on actual and forecasted net sales utilizing the prospective method. A significant increase or decrease in actual or forecasted net sales will materially impact the revenue interest liability, interest expense, and the time period for repayment.

Derivative Liabilities

Embedded derivatives that are required to be bifurcated from the underlying debt instrument that do not meet the derivative scope exception and equity classification criteria are accounted for and valued as separate financial instruments. The terms of an embedded derivative related to a contingent exercisable prepayment feature of a convertible note have been evaluated and deemed to require bifurcation. This embedded derivative was initially measured at fair value and is remeasured to fair value at each reporting date until the derivative is settled. On December 10, 2024, the company and Nant Capital entered into a second amended and restated promissory note (the $505.0 million December 2024 Promissory Note) for which the FVO method of accounting was elected. As such, the bifurcation of the embedded derivative is not required. The embedded derivative is now included within the fair value of the second amended and restated promissory note recorded in *related-party convertible note payable at fair value*, on the consolidated balance sheet.

In addition, the RIPA contains certain features that meet the definition of being an embedded derivative requiring bifurcation as a separate compound financial instrument apart from the RIPA. The derivative liability is initially measured at fair value upon issuance and is subject to remeasurement at each reporting period with changes in fair value recognized in *other income (expense, net*, on the consolidated statement of operations.

Research and Development Costs

Major components of research and development costs include cash compensation and other personnel-related expenses, stock-based compensation, depreciation and amortization expense on research and development property and equipment and intangible assets, costs of preclinical studies, clinical trials costs, including CROs and related clinical manufacturing, including third-party CMOs, costs of drug development, costs of materials and supplies, facilities cost, overhead costs, regulatory and compliance costs, and fees paid to consultants and other entities that conduct certain research and development activities on our behalf. Costs incurred in research and development are expensed as incurred.

The company classifies its research and development expenses as either external or internal. The company's external research and development expenses support its various preclinical and clinical programs. The company's internal research and development expenses include payroll and benefits expenses, facilities and equipment expense, and other indirect research and development expenses incurred in support of its research and development activities. The company's external and internal resources are not directly tied to any one research or drug discovery program and are typically deployed across multiple programs and are not allocated to specific product candidates or development programs.

Included in research and development costs are clinical trial and research expenses based on the services performed pursuant to contracts with research institutions and clinical research organizations and other vendors that conduct clinical trials and research on our behalf. We record accruals for estimated costs under these contracts. When evaluating the adequacy of the accrued liabilities, we analyze the progress of the preclinical studies or clinical trials, including the phase or completion of events, invoices received, contracted costs and purchase orders. Significant judgments and estimates are made in determining the accrued balances at the end of any reporting period based on the facts and circumstances known at that time. Although we do not expect the estimates to be materially different from the amounts actually incurred, if the estimates of the status and timing of services performed differ from the actual status and timing of services performed, we may report amounts that are too high or too low in any particular period. Actual results could differ from our estimates. We adjust the accruals in the period when actual costs become known.

Contingencies

We record accruals for loss contingencies to the extent that we conclude it is probable that a liability has been incurred and the amount of the related loss can be reasonably estimated. We accrue for the best estimate of a loss within a range; however, if no estimate in the range is better than any other, then we accrue the minimum amount in the range. If we determine that a material loss is reasonably possible, we disclose the possible loss or range of loss, or that the amount of loss cannot be estimated at this time. We evaluate, on a quarterly basis, developments in legal proceedings and other matters that could cause a change in the potential amount of the liability recorded or the range of potential losses disclosed. Moreover, we record gain contingencies only when they are realizable and the amount is known. Additionally, we record our rights to insurance recoveries, limited to the extent of incurred or probable losses, as a receivable when such recoveries have been agreed to with our third-party insurers and when receipt is deemed probable. This includes instances when our third-party insurers have agreed to pay, on our behalf, certain legal defense costs and settlement amounts directly to applicable law firms and a settlement fund.

Warrants

The company accounts for warrants as either equity-classified or liability-classified instruments based on an assessment of the warrant's specific terms and applicable authoritative guidance in FASB ASC Topic 480, *Distinguishing Liabilities from Equity* (ASC 480), and ASC 815. The assessment considers whether the warrants are freestanding financial instruments pursuant to ASC 480, meet the definition of a liability pursuant to ASC 480, and whether the warrants meet all of the requirements for equity classification under ASC 815, including whether the warrants are indexed to the company's own stock and whether the warrant holders could potentially require "net cash settlement" in a circumstance outside of the company's control, among other conditions for equity classification. This assessment, which requires the use of professional judgment, is conducted at the time of warrant issuance and as of each subsequent quarterly period end date while the warrants are outstanding.

For warrants that meet all criteria for equity classification, the warrants are required to be recorded as a component of *additional paid-in capital,* on the consolidated statement of stockholders' deficit at the time of issuance. For warrants that do not meet all the criteria for equity classification, the warrants are required to be recorded at their initial fair value on the date of issuance, and on each balance sheet date thereafter. Changes in the estimated fair value of the warrants are recognized as a non-cash gain or loss in *other income (expense), net*, on the consolidated statement of operations. The fair value of the warrants was estimated using the Black-Scholes option pricing model.

Fair Value Option Election

The company elected to apply the FVO method of accounting in line with ASC 825 and account for certain of its notes and embedded derivatives at fair value as a single instrument in accordance with ASC 815. The notes for which the FVO is elected are recorded at fair value upon the date of issuance and subsequently remeasured to fair value at each reporting period. Changes in the fair value of the notes accounted for at fair value are recorded as a component of *other income (expense), net,* on the consolidated statement of operations. Any changes in fair value caused by instrument-specific credit risk are recorded separately in *other comprehensive income (loss),* on the consolidated statement of comprehensive loss. The cumulative amount previously recorded in *other comprehensive income (loss)* resulting from changes in the instrument-specific credit risk for extinguished notes are reclassified and reported in current earnings on the consolidated statement of operations. All costs associated with the issuance of the convertible promissory note accounted for using the FVO were expensed upon issuance.

The company has applied the FVO on the $505.0 million December 2024 Promissory Note and $30.0 million March 2023 Promissory Note prior to its extinguishment on December 29, 2023. See Note 12 *"Related-Party Debt"* for more information. During the year ended December 31, 2024, the company recorded $1.2 million changes in fair value related to instrument-specific credit risk.

Debt Modification and Extinguishment

The company evaluates amendments to its debt instruments in accordance with ASC 470-50. This evaluation includes comparing (1) if applicable, the net present value of future cash flows of the amended debt to that of the original debt and (2) the change in fair value of an embedded conversion feature to that of the carrying amount of the debt immediately prior to amendment to determine, in each case, if a change greater than 10% occurred. In instances where the net present value of future cash flows or the fair value of an embedded conversion feature, if any, changed more than 10%, the company applies extinguishment accounting. In instances where the net present value of future cash flows and the fair value of an embedded conversion feature, if any, changed less than 10%, the company accounts for the amendment to the debt as a debt modification. Gains and losses on debt amendments that are considered extinguishments are recognized in current earnings or in additional paid-in capital if the transactions are with entities under common control. Debt amendments that are considered debt modifications are accounted for prospectively through yield adjustments, based on the revised terms. The increase in fair value of the embedded conversion feature from the debt modification was accounted for as an increase in debt discount with a corresponding increase in additional paid-in capital. Legal fees and other costs incurred with third parties that are directly related to debt modifications are expensed as incurred. Amounts paid by the company to the lenders, are reflected as additional debt discount and amortized as an adjustment of interest expense over remaining term of modified debt using the effective interest rate method.

Provision for Income Taxes

Our provision for income taxes is computed under the asset and liability method. Significant estimates are required in determining our provision for income taxes. Some of these estimates are based on interpretations of existing tax laws or regulations. We recognize deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements or tax returns. Under this method, deferred tax assets and liabilities are determined on the basis of the difference between the tax basis of assets and liabilities and their respective financial reporting amounts (temporary differences) at enacted tax rates in effect for the years in which the differences are expected to reverse. A valuation allowance is established for deferred tax assets for which it is more likely than not that some portion or all of the deferred tax assets, including net operating losses and tax credits, will not be realized. We periodically re-assess the need for a valuation allowance against our deferred tax assets based on various factors including our historical earnings experience by taxing jurisdiction, and forecasts of future operating results and utilization of net operating losses and tax credits prior to their expiration. Significant judgment is required in making this assessment and, to the extent that a reversal of any portion of our valuation allowance against our deferred tax assets is deemed appropriate, a tax benefit will be recognized against our provision for income taxes in the period of such reversal.

Stock-Based Compensation

We account for stock-based compensation under the provisions of FASB ASC Topic 718, *Compensation—Stock Compensation* (ASC 718). We estimate fair value of each stock option award on the date of grant using the Black-Scholes option pricing model. The Black-Scholes option pricing model requires the use of subjective assumptions, including, but not limited to, expected stock price volatility over the term of the awards and the expected term of the stock options. We measure the fair value of an equity-classified award at the grant date and recognize the stock-based compensation expense over the period of vesting on the straight-line basis for our outstanding share awards that do not contain a performance condition. For awards subject to performance-based vesting conditions, we assess the probability of the individual milestones under the award being achieved and stock-based compensation expense is recognized over the service period using the graded vesting method once management believes the performance criteria is probable of being met. For awards with service or performance conditions, we recognize the effect of forfeitures in compensation cost in the period that the award was forfeited.

Recent Accounting Pronouncements

See Note 2 *"Summary of Significant Accounting Policies"* of the "Notes to Consolidated Financial Statements" that appears in Part II, Item 8. "Financial Statements and Supplementary Data" of this Annual Report for a discussion of recent accounting pronouncements or changes in accounting pronouncements that are of significance, or potential significance, to us.

Other Company Information

Transition from Smaller Reporting Company Status

On December 31, 2024, we ceased to be a "smaller reporting company" because the market value of our common stock held by non-affiliates exceeded $700.0 million as of June 28, 2024. However, we are complying with certain scaled disclosure requirements available to smaller reporting companies in this Annual Report (including as incorporated by reference to the information contained in our Proxy Statement), which we are permitted to do under SEC rules because we were a smaller reporting company in 2024. As a result, the information that we provide to our stockholders may be different than what you might receive from other public reporting companies in which you hold equity interests.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

Our exposure to market risk for changes in interest rates relates primarily to interest earned on our cash equivalents, investments and variable interest rate debt. The primary objective of our investment activities is to preserve our capital to fund operations. A secondary objective is to maximize income from our investments without assuming significant risk. Our investment policy provides for investments in low-risk, investment-grade debt instruments. As of December 31, 2024, we had $143.4 million in cash and cash equivalents and $6.4 million in our investment portfolio. Our cash equivalents are short-term investments with maturities of 90 days or less at the time of purchase. We maintain cash deposits in FDIC insured financial institutions in excess of federally insured limits. However, we believe that we are not exposed to significant credit risk due to the financial position of the depository institutions in which those deposits are held. As of December 31, 2024, our investment portfolio was comprised of available-for-sale securities, and we did not hold or issue financial instruments for trading purposes.

Interest Rate Risk – Cash

With the cash discussed above, our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S interest rates. However, we do not believe a sudden change in the interest rates would have a material impact on our financial condition or results of operations due to the short-term maturities of our cash equivalents. A hypothetical 100 basis point change in interest rates during any of the periods presented would not have had a material impact on our consolidated financial statements.

Interest Rate Risk – Cash Equivalents and Investment Portfolio

We invest a portion of our cash in a number of diversified fixed-and floating-rate securities, consisting of marketable debt securities and debt funds that are subject to interest rate risk. Changes in the general level of interest rates can affect the fair value of our investment portfolio. If interest rates in the general economy were to rise, our holdings could lose value. At December 31, 2024, a hypothetical increase in interest rates of 100 basis points across the entire yield curve on our holdings would not have resulted in a material impact on the fair value of our portfolio.

Interest Rate Risk – Variable-Rate Debt

Our use of variable-rate debt exposes us to interest rate risk as changes in interest rates would affect interest expense. As of December 31, 2024, we have a $505.0 million variable-rate loan outstanding, which matures on December 31, 2027 and bears interest at Term SOFR plus 8.0% per annum.

As of December 31, 2024, the weighted-average interest rate on this loan was 12.34%. A hypothetical 100-basis point increase in the Term SOFR rate as of December 31, 2024 would increase our future interest payments by $15.2 million. Similarly, a hypothetical 100-basis point decrease in the Term SOFR rate as of December 31, 2024 would decrease our future interest payments by $15.2 million.

Interest Rate Risk – RIPA

We have entered into a revenue interest purchase agreement. Our primary exposure to market risk is that the interest rate on the revenue interest liability may vary during the term of the agreement depending on a number of factors, including the level of forecasted net sales. A significant increase or decrease in actual or forecasted net sales will materially impact the revenue interest liability, interest expense, and the time period for repayment. See Note 11 *"Revenue Interest Purchase Agreement"* that appears in Part II, Item 8. "Financial Statements and Supplementary Data" of this Annual Report for more information regarding the terms of the RIPA.

Foreign Currency Exchange Risk

We are exposed to foreign currency exchange rate risk inherent in conducting business globally in numerous currencies. We contract with clinical research organizations, investigational sites and suppliers in foreign countries. We are, therefore, subject to fluctuations in foreign currency rates in connection with these agreements. We have not entered into any material foreign currency hedging contracts although we may do so in the future. From inception through the date of this Annual Report, we have not incurred any material effects from foreign currency changes on these contracts. The effect of a 10% adverse change in exchange rates on foreign currency denominated cash and payables as of December 31, 2024 would not have been material. However, fluctuations in currency exchange rates could harm our business in the future.

We are also exposed to foreign currency fluctuations related to the operations of our subsidiary in Italy whose financial statements are denominated in the Euro. We translate all assets and liabilities denominated in foreign currency into U.S. dollars using the exchange rate as of the end of the reporting period, while the operating results are translated into U.S. dollars using the average exchange rates for the reporting periods. Gains and losses resulting from translating the financial statements from our subsidiary's functional currency to U.S. dollars are recognized as a component of *other comprehensive (loss) income*, on the consolidated statement of comprehensive loss. Foreign currency exchange rate fluctuations affect our reported net loss and can make comparisons from period to period more difficult. Our foreign operations are not material to our operations as a whole. As such, we currently do not enter into currency forward exchange or option contracts to hedge foreign currency exposures.

Market Risk

As of December 31, 2024, 6,399,171 warrants from our RDOs remained outstanding at a fair value of $8.6 million. The fair value of the warrant liabilities is determined using the Black-Scholes option pricing model and is therefore sensitive to changes in the market price and volatility of our common stock among other factors. In the event of a hypothetical 10% increase in the market price of our common stock ($2.82 based on the $2.56 market price of our stock at December 31, 2024) on which the December 31, 2024 valuation was based, the fair value of the warrant liabilities would have increased by $1.3 million. Similarly, based on the fair value of the warrants outstanding as of December 31, 2024, a hypothetical 10% decrease in the market price of our common stock would have decreased the fair value of the warrant liabilities by $1.2 million. Such increase or decrease would have been reflected as a change in fair value of warrant liabilities in *other income (expense), net*, on the consolidated statement of operations.

Inflation Risk

Inflation may affect us by increasing our cost of labor, clinical trial, and other costs. We do not believe that inflation has had a material effect on our business, financial condition or results of operations for any period presented herein.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of ImmunityBio, Inc. and Subsidiaries

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of ImmunityBio, Inc. and Subsidiaries (the Company) as of December 31, 2024 and 2023, the related consolidated statements of operations, comprehensive loss, stockholders' deficit and cash flows for each of the three years in the period ended December 31, 2024, 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 each of the three years in the period ended December 31, 2024, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2024, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework), and our report dated March 3, 2025 expressed an unqualified opinion thereon.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the 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 financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the 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 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 financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the account or disclosure to which it relates.

Related party transactions and disclosures

Description of the Matter	As described in Notes 12 and 13 to the consolidated financial statements, the Company's Founder, Executive Chairman and Global Chief Scientific and Medical Officer Dr. Patrick Soon-Shiong has a controlling interest in certain entities with which the Company has entered into material transactions including related-party debt transactions with Nant Capital, LLC. Affiliates of such entities are also affiliates of the Company due to the common control of the Company's Founder, Executive Chairman and Global Chief Scientific and Medical Officer. Assessing the sufficiency of procedures performed to identify related parties and significant related-party transactions and determining the identified significant related-party transactions were properly recorded, presented and disclosed was challenging due to the nature, volume and the significance of related-party transactions.
How We Addressed the Matter in Our Audit	We obtained an understanding, evaluated the design, and tested the operating effectiveness of internal controls over the Company's related-party process. This included testing controls over management's identification, review, recognition and disclosure of significant related-party transactions. The audit procedures we performed included, among others, testing the completeness and accuracy of the listing of related parties identified and significant related-party transactions provided by management, and testing the manner in which significant related party transactions were recorded, presented and disclosed. We performed journal entry searches of identified related parties to verify completeness and accuracy of the Company's significant related-party transactions. We inquired of management, members of the Company's audit committee, and the Company's related-party transaction committee chair regarding the completeness of the significant related-party transactions identified. We also inspected questionnaires received from the Company's directors and officers, read minutes of the meetings of Board of Directors and its various Committees, read employment and compensation contracts, proxy statements and other relevant filings with the Securities and Exchange Commission that relate to the Company's financial relationships and transactions with the Company's executive officers and with other entities controlled by the Company's Founder, Executive Chairman and Global Chief Scientific and Medical Officer. We confirmed the significant transactions and/or balances, as applicable, with the related parties. We also obtained the underlying agreements for significant related-party transactions and assessed the associated accounting and recognition. We involved valuation specialists to assist in evaluating the appropriateness of the valuation methodologies and reasonableness of the assumptions used in the valuation of the related-party debt including underlying conversion features, as described in Note 12 to the consolidated financial statements.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2016.

Los Angeles, California
March 3, 2025

ImmunityBio, Inc. and Subsidiaries
Consolidated Balance Sheets
(in thousands, except share and per share amounts)

	As of December 31,	
	2024	2023
ASSETS		
Current assets:		
Cash and cash equivalents	$ 143,428	$ 265,453
Marketable securities	6,381	1,009
Accounts receivable, net	2,360	—
Inventories	8,272	—
Due from related parties	293	2,019
Prepaid expenses and other current assets (including amounts with related parties)	23,852	25,603
Total current assets	184,586	294,084
Marketable securities, noncurrent	—	891
Property, plant and equipment, net	137,094	146,082
Goodwill and intangible assets, net	15,933	17,093
Convertible note receivable	7,130	6,879
Operating lease right-of-use assets, net (including amounts with related parties)	33,363	36,543
Other assets (including amounts with related parties)	4,827	2,880
Total assets	$ 382,933	$ 504,452
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	$ 6,725	$ 9,195
Accrued expenses and other liabilities	40,580	42,708
Due to related parties	173	1,136
Operating lease liabilities (including amounts with related parties)	7,466	5,244
Total current liabilities	54,944	58,283
Related-party nonconvertible note, net of discount (Note 12)	—	104,586
Related-party convertible notes and accrued interest, net of discount (Note 12)	—	576,951
Related-party convertible note payable, at fair value (Note 7 and Note 12)	461,877	—
Revenue interest liability (Note 11)	284,404	155,415
Derivative liabilities (Note 11 and Note 12)	25,800	35,333
Operating lease liabilities, less current portion (including amounts with related parties)	34,823	39,942
Warrant liabilities	8,575	118,770
Other liabilities	639	1,109
Total liabilities	871,062	1,090,389
Commitments and contingencies (Note 9)		
Stockholders' deficit:		
Common stock, $0.0001 par value; 1,350,000,000 shares authorized as of December 31, 2024 and 2023; 852,904,340 and 670,867,344 shares issued and outstanding as of December 31, 2024 and 2023, respectively; excluding 163,800 treasury stock shares outstanding as of December 31, 2024 and 2023	85	67
Additional paid-in capital	2,884,867	2,374,620
Accumulated deficit	(3,375,248)	(2,961,684)
Accumulated other comprehensive income	1,198	10
Total ImmunityBio stockholders' deficit	(489,098)	(586,987)
Noncontrolling interests	969	1,050
Total stockholders' deficit	(488,129)	(585,937)
Total liabilities and stockholders' deficit	$ 382,933	$ 504,452

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

ImmunityBio, Inc. and Subsidiaries
Consolidated Statements of Operations
(in thousands, except per share amounts)

	Year Ended December 31,		
	2024	2023	2022
Revenue			
Product revenue, net	$ 14,150	$ —	$ —
Other revenues	595	622	240
Total revenue	14,745	622	240
Operating costs and expenses			
Cost of sales	—	—	—
Research and development (including amounts with related parties)	190,144	232,366	248,149
Selling, general and administrative (including amounts with related parties)	168,783	129,620	102,708
Impairment of intangible assets	—	886	681
Total operating costs and expenses	358,927	362,872	351,538
Loss from operations	(344,182)	(362,250)	(351,298)
Other income (expense), net:			
Interest and investment income (loss), net	7,975	1,131	(3,090)
Interest expense (including amounts with related parties)	(114,670)	(128,934)	(63,515)
Change in fair value of related-party convertible notes	43,472	(36,203)	—
Interest expense related to revenue interest liability	(39,657)	(264)	—
Change in fair value of warrant liabilities	19,955	(47,600)	13,460
Change in fair value of derivative liabilities	13,477	—	—
Loss on equity method investment	—	(7,549)	(12,107)
Other expense, net (including amounts with related parties)	(15)	(2,223)	(736)
Total other income (expense), net	(69,463)	(221,642)	(65,988)
Loss before income taxes and noncontrolling interests	(413,645)	(583,892)	(417,286)
Income tax benefit (expense)	—	40	(34)
Net loss	(413,645)	(583,852)	(417,320)
Net loss attributable to noncontrolling interests, net of tax	(81)	(656)	(753)
Net loss attributable to ImmunityBio common stockholders	$ (413,564)	$ (583,196)	$ (416,567)
Net loss per ImmunityBio common share – basic	$ (0.59)	$ (1.15)	$ (1.04)
Net loss per ImmunityBio common share – diluted	$ (0.62)	$ (1.15)	$ (1.04)
Weighted-average number of common shares used in computing net loss per share – basic	697,312	508,636	399,900
Weighted-average number of common shares used in computing net loss per share – diluted	700,443	508,636	399,900

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

ImmunityBio, Inc. and Subsidiaries
Consolidated Statements of Comprehensive Loss
(in thousands)

	Year Ended December 31,		
	2024	2023	2022
Net loss	$ (413,645)	$ (583,852)	$ (417,320)
Other comprehensive income (loss), net of income taxes:			
Change in fair value of related-party convertible note related to instrument-specific credit risk	1,221	—	—
Net unrealized gains (losses) on available-for-sale securities	15	60	(183)
Reclassification of net realized gains (losses) on available-for-sale securities included in net loss	42	(15)	124
Foreign currency translation adjustments	(90)	(218)	238
Total other comprehensive income (loss)	1,188	(173)	179
Comprehensive loss	(412,457)	(584,025)	(417,141)
Less: Comprehensive loss attributable to noncontrolling interests	81	656	753
Comprehensive loss attributable to ImmunityBio common stockholders	$ (412,376)	$ (583,369)	$ (416,388)

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

ImmunityBio, Inc. and Subsidiaries
Consolidated Statements of Stockholders' Deficit
(in thousands, except share amounts)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total ImmunityBio Stockholders' Deficit	Noncontrolling Interests	Total Stockholders' Deficit
	Shares	Amount						
Balance as of December 31, 2021	397,830,044	$ 40	$ 1,719,704	$ (1,961,921)	$ 4	$ (242,173)	$ (1,740)	$ (243,913)
Issuance of common stock "at-the-market" offering, net of commissions and offering costs of $302	2,051,894	—	13,129	—	—	13,129	—	13,129
Conversion of related-party convertible note and accrued interest, net of unamortized debt discount, into equity	9,986,920	1	51,946	—	—	51,947	—	51,947
Issuance of shares in an RDO, net of discount and offering costs of $1,897 and value ascribed to associated warrants	9,090,909	1	13,006	—	—	13,007	—	13,007
Stock-based compensation expense	—	—	40,179	—	—	40,179	—	40,179
Exercise of stock options	14,767	—	74	—	—	74	—	74
Vesting of RSUs	521,296	—	—	—	—	—	—	—
Net share settlement for RSUs vesting	(156,011)	—	(616)	—	—	(616)	—	(616)
Shares issued pursuant to litigation settlement	2,229,296	—	10,656	—	—	10,656	—	10,656
Gain on extinguishment of debt with related parties under common control	—	—	82,858	—	—	82,858	—	82,858
Other comprehensive income (loss), net of tax	—	—	—	—	179	179	—	179
Net loss	—	—	—	(416,567)	—	(416,567)	(753)	(417,320)
Balance as of December 31, 2022	421,569,115	42	1,930,936	(2,378,488)	183	(447,327)	(2,493)	(449,820)

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

ImmunityBio, Inc. and Subsidiaries
Consolidated Statements of Stockholders' Deficit (Continued)
(in thousands, except share amounts)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total ImmunityBio Stockholders' Deficit	Noncontrolling Interests	Total Stockholders' Deficit
	Shares	Amount						
Issuance of common stock "at-the market" offering, net of commissions and offering costs of $457	5,605,323	1	16,105	—	—	16,106	—	16,106
Issuance of common stock in exchange for notes payable	209,291,936	21	269,966	—	—	269,987	—	269,987
Issuance of shares in RDOs, net of discounts and offering costs of $3,535 and value ascribed to associated warrants	28,641,911	3	36,928	—	—	36,931	—	36,931
Issuance of common stock in connection with the RIPA, net of transaction costs of $473	2,432,894	—	11,581	—	—	11,581	—	11,581
Gain on debt extinguishment with related-parties under common control	—	—	36,110	—	—	36,110	—	36,110
Increase in fair value of embedded conversion feature from debt modification with entities under common control	—	—	31,179	—	—	31,179	—	31,179
Stock-based compensation expense	—	—	49,163	—	—	49,163	—	49,163
Exercise of stock options	184,362	—	294	—	—	294	—	294
Vesting of RSUs	4,545,644	—	—	—	—	—	—	—
Net share settlement for RSUs vesting	(1,403,841)	—	(3,443)	—	—	(3,443)	—	(3,443)
Change in ownership interest in a joint venture due to legal settlement	—	—	(4,199)	—	—	(4,199)	4,199	—
Other comprehensive income (loss), net of tax	—	—	—	—	(173)	(173)	—	(173)
Net loss	—	—	—	(583,196)	—	(583,196)	(656)	(583,852)
Balance as of December 31, 2023	670,867,344	67	2,374,620	(2,961,684)	10	(586,987)	1,050	(585,937)

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

ImmunityBio, Inc. and Subsidiaries
Consolidated Statements of Stockholders' Deficit (Continued)
(in thousands, except share amounts)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total ImmunityBio Stockholders' Deficit	Noncontrolling Interests	Total Stockholders' Deficit
	Shares	Amount						
Issuance of common stock "at-the-market" offering, net of commissions and offering costs of $660	427,368	—	3,625	—	—	3,625	—	3,625
Conversion of related-party convertible notes and accrued interest into equity	117,185,260	11	188,526	—	—	188,537	—	188,537
Issuance of shares in an equity offering, net of offering costs of $8,073	38,333,334	4	106,923	—	—	106,927	—	106,927
Gain on debt extinguishment with related-parties under common control	—	—	10,418	—	—	10,418	—	10,418
Stock-based compensation expense	—	—	34,432	—	—	34,432	—	34,432
Exercise of stock options	308,959	—	715	—	—	715	—	715
Vesting of RSUs	4,269,864	—	—	—	—	—	—	—
Net share settlement for RSUs vesting	(1,589,519)	—	(5,465)	—	—	(5,465)	—	(5,465)
Exercise of warrants	22,242,740	3	163,519	—	—	163,522	—	163,522
Exercise of Oberland stock option, net of commissions of $150	858,990	—	7,554	—	—	7,554	—	7,554
Other comprehensive income (loss), net of tax	—	—	—	—	1,188	1,188	—	1,188
Net loss	—	—	—	(413,564)	—	(413,564)	(81)	(413,645)
Balance as of December 31, 2024	852,904,340	$ 85	$ 2,884,867	$ (3,375,248)	$ 1,198	$ (489,098)	$ 969	$ (488,129)

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

ImmunityBio, Inc. and Subsidiaries
Consolidated Statements of Cash Flows
(in thousands)

	Year Ended December 31,		
	2024	2023	2022
Operating activities:			
Net loss	$ (413,645)	$ (583,852)	$ (417,320)
Adjustments to reconcile net loss to net cash used in operating activities:			
Change in fair value of convertible note	(43,472)	36,203	—
Non-cash interest expense related to the revenue interest liability	38,004	264	—
Stock-based compensation expense	34,432	49,163	40,179
Amortization of related-party notes discounts	22,587	42,396	16,282
Change in fair value of warrant liabilities	(19,955)	47,600	(13,460)
Depreciation and amortization	17,554	18,512	18,260
Change in fair value of derivative liabilities	(13,477)	—	—
Non-cash lease expense related to operating lease right-of-use assets	5,756	6,112	5,932
Accretion of discounts on marketable debt securities	(1,489)	(137)	1,318
Non-cash interest items, net (including amounts with related parties)	1,150	8,925	11,746
Unrealized losses on equity securities	632	1,591	4,190
Transaction costs allocated to warrant liabilities	—	2,010	1,082
Impairment of intangible assets	—	886	681
Impairment of fixed assets	—	—	1,333
Other	109	(407)	269
Changes in operating assets and liabilities:			
Accounts receivable	(2,360)	—	—
Inventories	(8,272)	—	—
Prepaid expenses and other current assets	1,703	5,958	(16,557)
Other assets	(1,108)	1,913	1,998
Accounts payable	(3,167)	(6,476)	8,000
Accrued expenses and other liabilities	(1,508)	6,689	4,102
Related parties	763	(1,129)	(1,225)
Operating lease liabilities	(5,473)	(2,978)	(4,319)
Net cash used in operating activities	(391,236)	(366,757)	(337,509)
Investing activities:			
Purchases of marketable debt securities, available-for-sale	(140,218)	(10,358)	(34,312)
Proceeds from maturities of marketable debt securities, available-for-sale	115,586	10,100	128,188
Proceeds from sales of marketable debt and equity securities	21,021	372	33,812
Purchases of property, plant and equipment	(6,888)	(30,584)	(78,162)
Acquisition of a business, net of transaction costs	(1,000)	—	—
Cash paid for other investments	(747)	—	—
Purchase of intangible assets	—	—	(21,229)
Investment in joint venture – an equity method investment	—	—	(1,000)
Net cash (used in) provided by investing activities	(12,246)	(30,470)	27,297

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

ImmunityBio, Inc. and Subsidiaries
Consolidated Statements of Cash Flows (Continued)
(in thousands)

	Year Ended December 31,		
	2024	2023	2022
Financing activities:			
Proceeds from equity offerings, net of discounts and issuance costs	$ 111,357	$ 100,561	$ 60,427
Proceeds from the RIPA, net of issuance costs	96,956	192,764	—
Proceeds from exercises of warrants	73,281	—	—
Net share settlement for RSUs vesting	(5,465)	(3,443)	(616)
Proceeds from exercise of Oberland stock option, net of commissions	4,850	—	—
Proceeds from exercises of stock options	715	294	74
Principal payments of finance leases	(64)	(77)	(58)
Proceeds from issuance of related-party promissory notes net of issuance costs paid	—	258,700	174,125
Proceeds from stock issuance in connection with the RIPA, net of transaction costs	—	9,542	—
Payment for contingent consideration	—	—	(339)
Net cash provided by financing activities	281,630	558,341	233,613
Effect of exchange rate changes on cash and cash equivalents, and restricted cash	(23)	(292)	284
Net change in cash and cash equivalents, and restricted cash	(121,875)	160,822	(76,315)
Cash and cash equivalents, and restricted cash, beginning of year	265,787	104,965	181,280
Cash and cash equivalents, and restricted cash, end of year	$ 143,912	$ 265,787	$ 104,965

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

ImmunityBio, Inc. and Subsidiaries
Consolidated Statements of Cash Flows (Continued)
(in thousands)

	Year Ended December 31,		
	2024	2023	2022
Reconciliation of cash and cash equivalents, and restricted cash, end of year:			
Cash and cash equivalents	$ 143,428	$ 265,453	$ 104,641
Restricted cash (Note 2)	484	334	324
Cash and cash equivalents, and restricted cash, end of year	$ 143,912	$ 265,787	$ 104,965
Supplemental disclosure of cash flow information:			
Cash paid during the year for:			
Interest	$ 92,318	$ 77,192	$ 35,442
Income taxes	$ 15	$ 8	$ 2
Supplemental disclosure of non-cash activities:			
Conversion of related-party convertible notes and accrued interest, net of unamortized discount, into equity	$ 188,537	$ 269,987	$ 51,947
Gain on debt extinguishment with related-parties under common control	$ 10,418	$ 36,110	$ 82,858
Right-of-use assets obtained in exchange for operating lease liabilities	$ 2,576	$ —	$ 14,798
Unpaid offering and transaction costs included in accounts payable and accrued expenses	$ 805	$ 255	$ 277
Property and equipment purchases included in accounts payable, accrued expenses and due to related parties	$ 748	$ 1,156	$ 12,693
Initial measurement of warrants issued in connection with RDOs accounted for as liabilities	$ —	$ 49,534	$ 35,096
Increase in fair value of embedded conversion feature from debt modification	$ —	$ 31,179	$ —
Change in ownership interest in a joint venture due to legal settlement	$ —	$ 4,199	$ —
Right-of-use assets disposed in exchange for operating lease liabilities	$ —	$ (3,777)	$ —
Common stock issuance discount related to the revenue interest liability	$ —	$ 2,039	$ —
Common stock issued pursuant to litigation settlement	$ —	$ —	$ 10,656

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

1. Description of Business

In these notes to the consolidated financial statements, the terms "ImmunityBio," "the company," "we," "us," and "our" refer to ImmunityBio and subsidiaries.

Our Business

ImmunityBio is a vertically-integrated commercial stage biotechnology company developing next-generation therapies that bolster the natural immune system to defeat cancers and infectious diseases. The company's range of immunotherapy platforms, alone and together, act to drive an immune response with the goal of creating durable immune memory generating safe protection against disease. We are applying our science and platforms to treating cancers, including the development of potential cancer vaccines, as well as developing immunotherapies and cell therapies that we believe sharply reduce or eliminate the need for standard high-dose chemotherapy. These platforms and their associated product candidates are designed to be more effective, accessible, and easily administered than current standards of care in oncology and infectious diseases.

Our platforms and their associated product and product candidates are designed to attack cancer and infectious pathogens by activating both the innate immune system, including NK cells, dendritic cells, and macrophages, as well as the adaptive immune system comprising B and T cells, in an orchestrated manner. The goal of this potentially best-in-class approach is to generate immunogenic cell death thereby eliminating rogue cells from the body whether they are cancerous or virally-infected. Our ultimate goal is to overcome the limitations of current treatments, such as CPIs, by turning immunologically cold, MHC-deficient tumors hot and/or reducing the need for standard high-dose chemotherapy in cancer by employing a coordinated approach to establish "immunological memory" that confers long-term benefit for the patient.

Our proprietary platforms for the development of biologic products and product candidates include: (i) cytokine fusion proteins, (ii) vaccine vectors, and (iii) cell therapies. Specifically, our core clinical focus is on bladder and lung cancers with additional clinical efforts in prostate and colorectal cancers, hematologic malignancies and GBM, which are among the most frequent and lethal cancer types, and where there are high failure rates for existing standards of care or no available effective treatment.

Our lead biologic product ANKTIVA is a novel first-in-class IL-15 receptor superagonist antibody-cytokine fusion protein. On April 22, 2024, the FDA approved our product, ANKTIVA with BCG for the treatment of adult patients with BCG-unresponsive NMIBC with CIS with or without papillary tumors. ANKTIVA was approved with a label indicating an immunological mechanism of action which proliferates and activates NK, CD8+ and memory T cells without the proliferation of immunosuppressive T-reg cells. We began commercial distribution of our approved product in May 2024.

2. Summary of Significant Accounting Policies

Basis of Presentation

The consolidated financial statements have been prepared in accordance with U.S. GAAP and pursuant to the rules and regulations of the SEC. Certain items in prior years consolidated financial statements have been reclassified to conform to the current presentation. These reclassifications had no effect on the reported results of operations. The consolidated financial statements reflect all adjustments which are, in the opinion of management, necessary for a fair presentation of our financial position and results of operations.

Principles of Consolidation

The accompanying consolidated financial statements include the accounts of the company, its wholly-owned subsidiaries, and a VIE for which the company is the primary beneficiary. Any material intercompany transactions and balances have been eliminated upon consolidation. For consolidated entities in which we have less than 100% ownership, we record *net loss attributable to noncontrolling interests, net of tax,* on the consolidated statement of operations equal to the percentage of the ownership interest retained in such entities by the respective noncontrolling parties.

We assess whether we are the primary beneficiary of a VIE at the inception of the arrangement and at each reporting date. This assessment is based on our power to direct the activities of the VIE that most significantly impact the VIE's economic performance and our obligation to absorb losses or the right to receive benefits from the VIE that could potentially be significant to the VIE.

If the entity is within the scope of the variable interest model and meets the definition of a VIE, we consider whether we must consolidate the VIE or provide additional disclosures regarding our involvement with the VIE. If we determine that we are the primary beneficiary of the VIE, we will consolidate the VIE. This analysis is performed at the initial investment in the entity or upon any reconsideration event.

For entities we hold as an equity investment that are not consolidated under the VIE model, we consider whether our investment constitutes a controlling financial interest in the entity and therefore should be considered for consolidation under the voting interest model.

Liquidity

As of December 31, 2024, the company had an accumulated deficit of $3.4 billion. We also had negative cash flows from operations of $391.2 million during the year ended December 31, 2024. The company will need to obtain additional financing to fund our future operations, including the commercialization of our approved product and the development and commercialization of our other product candidates.

The consolidated financial statements have been prepared assuming the company will continue as a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business, and do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or amounts and classification of liabilities that may result from the outcome of the uncertainty of our ability to continue as a going concern. As a result of continuing anticipated operating cash outflows as we commercialize our approved product and accelerate our development efforts, we believe that substantial doubt exists regarding our ability to continue as a going concern without additional funding or financial support. However, we believe our existing cash and cash equivalents, and investments in marketable securities; sales of our approved product; capital to be raised through equity offerings; and our potential ability to borrow from affiliated entities will be sufficient to fund our operations through at least the next 12 months following the issuance date of the consolidated financial statements based primarily upon our Founder, Executive Chairman and Global Chief Scientific and Medical Officer's intent and ability to support our operations with additional funds, including loans from affiliated entities, as required, which we believe alleviates such doubt.

In addition to funds from the future sales of our approved product, which we expect to take time to establish, we may also seek to sell additional equity, through one or more follow-on offerings, or in separate financings, or obtain incremental subordinated debt in compliance with our existing revenue interest liability. However, we may not be able to secure such external financing in a timely manner or on favorable terms. Without significant sales of our approved product or additional funds, we may choose to delay or reduce our operating or investment expenditures. Further, because of the risk and uncertainties associated with the commercialization of our approved product and our other product candidates, we may need additional funds to meet our needs sooner than planned.

Use of Estimates

The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to make certain estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. On an ongoing basis, we evaluate our estimates and the assessment of our ability to fund our operations for at least the next 12 months from the date of issuance of these consolidated financial statements. We base our estimates on historical experience and on various other market-specific and relevant assumptions that we believe to be reasonable under the circumstances. Estimates are assessed each period and updated to reflect current information and anticipated future events, and accordingly, actual results may ultimately differ materially from those estimates.

Revenue Recognition

Product Revenue, Net

After FDA approval in April 2024, the company began recognizing revenue from the sale of ANKTIVA in accordance with ASC 606. The provisions of ASC 606 require the following steps to determine revenue recognition: (i) identification of contract with the customers; (ii) identification of performance obligations; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations based on estimated selling prices; and (v) recognition of revenue when (or as) we satisfy each performance obligation. At contract inception, we assess the goods or services promised within each contract, determine whether each promised good or service is distinct and identify those that are performance obligations. We recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

The company entered into a third-party logistics agreement to engage a 3PL Agent to distribute the company's products to its customers. The 3PL Agent provides services to the company that include storage, shipping and distribution, processing product returns, as well as customer service, order to cash, and logistics support. The company's customers are currently limited to pharmaceutical specialty distributors and specialty pharmacy. The company primarily sells ANKTIVA to specialty distributors through a drop-ship arrangement under which orders from various healthcare institutions such as hospitals, medical facilities, physician practices, pharmacies and government agencies are processed through and controlled by specialty distributors. Under the drop-ship arrangement, the 3PL Agent ships the product to various health care institutions without the specialty distributor ever taking physical possession of the product. The company recognizes product revenue when ANKTIVA is delivered to the end user as instructed and controlled by specialty distributors.

The company also sells ANKTIVA directly to a specialty pharmacy who then subsequently distributes ANKTIVA to physicians, clinics, and certain medical centers, hospitals or other healthcare institutions. The company recognizes product revenue when ANKTIVA is delivered to the specialty pharmacy location.

Product revenue is recorded with each sale at wholesale acquisition cost, net of: (a) consideration payable to customers; and (b) variable considerations. The company pays fees to the specialty distributors for certain administrative services associated with the distribution of the product wherein the terms of which are also detailed in its contracts. Such fees are not for a distinct good or service and, accordingly, are recorded as a reduction of revenue, as well as a reduction of accounts receivable (trade discounts) or as a component of accrued expenses (distributor fees). The variable consideration components include, but are not limited to, prompt payment discounts, product returns, chargebacks, rebates, and co-payment assistance, which are collectively referred to as "Gross-to-Net Adjustments." In accordance with ASC 606, the company must make significant judgments to determine the estimates for certain variable considerations. Variable consideration is included in the transaction price only to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved. The company utilizes the expected value method when estimating the amount of variable consideration to include in the transaction price with respect to each of the foregoing variable consideration components. Where appropriate, these estimates are based on factors such as industry and forecasted customer buying and payment patterns, our experience, current contractual and statutory requirements, and specific known market events and trends.

Variable considerations are reassessed each reporting period, and adjustments are recorded on a cumulative catch-up basis, which affects product revenue and net income in the period of adjustment. The actual amounts of variable consideration ultimately received may differ from our estimates. If actual results in future periods vary from our estimates, we adjust these estimates accordingly. As we gain more experience, estimates will be more heavily based on the expected utilization from historical data we have accumulated since the ANKTIVA product launch. The consideration payable to customers and contingent considerations reflect our best estimates of the amount of consideration to which we are entitled based on the terms of the contracts.

Other Revenues

Prior to the approval of ANKTIVA for commercial sale, we primarily generated revenues from non-exclusive license agreements related to our cell lines, the sale of our bioreactors and related consumables, and grant programs. The company expects to continue to generate revenue from these programs.

We sell our proprietary GMP-in-a-Box bioreactors and related consumables to affiliated companies and third parties. The arrangements typically include delivery of bioreactors, consumables, and providing installation service and perpetual software licenses for using the equipment. We recognize revenue when customers obtain control and can benefit from the promised goods or services, generally upon installation of the bioreactors, in an amount that reflects the consideration that we expect to receive in exchange for those goods or services. Upfront payments and fees are recorded as deferred revenue upon receipt and recognized as revenue when we satisfy our performance obligations under these arrangements.

Grant revenue is typically paid for reimbursable costs incurred over the duration of the associated research project or clinical trial and is recognized either when expenses reimbursable under the grants have been incurred and payments under the grants become contractually due or when cash is received, depending on the certainty of payment and other factors specific to each grant.

License Agreements with Third Parties

The company has nonexclusive license agreements with a limited number of pharmaceutical and biotechnology companies that grant them the right to use our cell lines and intellectual property for non-clinical use. These agreements generally include upfront fees and annual research license fees for such use, as well as commercial license fees for sales of the licensee products developed or manufactured using our intellectual property and cell lines.

Under our license agreements with customers, we typically promise to provide a license to use certain cell lines and related patents, the related know-how, and future research and development data that affect the license. We have concluded that these promises represent a single performance obligation due to the highly interrelated nature of the promises. We provide the cell lines and know-how immediately upon entering into the contracts. Research and development data are provided throughout the term of the contract when and if available. A performance obligation is a promise in a contract to transfer a distinct good or service to the customer. A contract's transaction price is allocated to each distinct performance obligation based on relative standalone selling price and recognized as revenue when, or as, the performance obligation is satisfied.

Our license agreements may include non-refundable upfront payments, event-based milestone payments, sales-based royalty payments, or some combination of these. The event-based milestone payments represent variable consideration, and we use the most likely amount method to estimate this variable consideration. Given the high degree of uncertainty around the achievement of these milestones, we do not recognize revenue from these milestone payments until the uncertainty associated with these payments is resolved. We currently estimate variable consideration related to milestone payments to be zero and, as such, no revenue has been recognized for milestone payments. We recognize revenue from sales-based royalty payments when or as sales occur. On a quarterly basis, we re-evaluate our estimate of milestone variable consideration to determine whether any amount should be included in the transaction price and recorded in revenue prospectively.

Cost of Sales

Cost of sales consists primarily of third-party manufacturing costs, distribution, and overhead costs related to sales of approved product subsequent to receiving regulatory approval. Cost of sales may also include costs related to excess or obsolete inventory adjustment charges, abnormal costs, unabsorbed manufacturing and overhead costs, and manufacturing variances. All costs associated with the production of ANKTIVA prior to receiving regulatory approval were expensed in *research and development expense*, on the consolidated statement of operations in the period incurred and therefore are not reflected in cost of sales.

Accounts Receivable, Net

Accounts receivable is recorded net of allowances for prompt payment discounts, product returns, chargebacks, and credit losses. The company estimates an allowance for credit losses by considering factors such as credit quality, the age of the accounts receivable balances, and current economic conditions that may affect a customer's ability to pay. As of December 31, 2024, the credit profile for the company's counterparty was deemed to be in good standing, and as such an allowance for credit losses was not recorded.

Inventories

Inventories are stated at the lower of cost or net realizable value. Cost, which includes amounts related to materials, labor and overhead, is determined in a manner that approximates the first-in, first-out method. Net realizable value is the estimated selling price in the ordinary course of business less reasonably predictable costs of completion, disposal and transportation. See Note 4 "*Inventories"* for more information.

Contingencies

We record accruals for loss contingencies to the extent that we conclude it is probable that a liability has been incurred, and the amount of the related loss can be reasonably estimated. We accrue for the best estimate of a loss within a range; however, if no estimate in the range is better than any other, then we accrue the minimum amount in the range. If we determine that a material loss is reasonably possible, we disclose the possible loss or range of loss, or that the amount of loss cannot be estimated at this time. We evaluate, on a quarterly basis, developments in legal proceedings and other matters that could cause a change in the potential amount of the liability recorded or the range of potential losses disclosed. Moreover, we record gain contingencies only when they are realizable, and the amount is known. Additionally, we record our rights to insurance recoveries, limited to the extent of incurred or probable losses, as a receivable when such recoveries have been agreed to with our third-party insurers and when receipt is deemed probable. This includes instances when our third-party insurers have agreed to pay, on our behalf, certain legal defense costs and settlement amounts directly to applicable law firms and a settlement fund.

Concentration of Major Customers

The company relies heavily on the limited number of customers to market and distribute ANKTIVA to various healthcare institutions or end users through the drop-ship arrangement. For the year ended December 31, 2024, approximately 92% of our total gross revenue was from our top three customers. The largest customer accounted for 38% of our total revenue, while the second and third largest accounted for 29% and 25%, respectively. As of December 31, 2024, our accounts receivable, net are mainly from sales of ANKTIVA, and the majority are from specialty distributors.

Our dependency on a few key customers exposes us to several risks, including the potential for disruptions in our distribution network, changes in customers' business strategies, or financial difficulties faced by these customers. Any significant disruption or change in our relationship with these customers could materially and adversely affect our ability to effectively reach other potential end users and maintain our market position. Additionally, we maintain regular communication and strong relationships with our existing customers to ensure alignment with our business objectives.

While we believe our relationships with these customers are strong and mutually beneficial, there can be no assurance that we will be able to maintain these relationships or that we will be able to replace them with new specialty distributors if necessary.

Concentration of Credit Risk and Other Risks and Uncertainties

Financial instruments that potentially subject us to concentration of risk consist principally of cash and cash equivalents, marketable securities, accounts receivable and a convertible note receivable.

We attempt to minimize credit risk associated with our cash and cash equivalents by periodically evaluating the credit quality of our primary financial institutions. Our investment portfolio is maintained in accordance with our investment policy. While we maintain cash deposits in FDIC insured financial institutions in excess of federally insured limits, we do not believe that we are exposed to significant credit risk due to the financial position of the depository institutions in which those deposits are held. We have not experienced any losses on such accounts.

We also monitor the creditworthiness of the borrower of the convertible note receivable. We believe that any concentration of credit risk in its convertible note receivable was mitigated in part by our ability to convert, if necessary, at the qualifying financing event or upon a payment default into shares of the senior class of equity securities of the borrower.

Product candidates developed by us will require approvals or clearances from the FDA or international regulatory agencies prior to commercial sales. There can be no assurance that any of our product candidates will receive any of the required approvals or clearances. If we were to be denied approval or clearance or any such approval or clearance was to be delayed, it would have a material adverse impact on us.

Cash, Cash Equivalents, and Restricted Cash

Cash equivalents include highly liquid investments with an original maturity of three months or less from the date of purchase.

Restricted cash includes a certificate of deposit held as a substitute letter of credit for one of our leased properties. This certificate of deposit is included in *other assets,* on the consolidated balance sheet as the landlord is the beneficiary of the account and we are not able to access the funds during the term of the lease.

A reconciliation of cash, cash equivalents, and restricted cash is included on the consolidated statements of cash flows as of December 31, 2024, 2023 and 2022.

Marketable Securities and Other Investments

Marketable Debt Securities

We have typically invested our cash in a variety of financial instruments, including investment-grade short- to intermediate-term corporate debt securities, government-sponsored securities and European bonds; however, after our entry into the RIPA, we can no longer invest our excess funds in corporate or European bonds. Certain of our investments are subject to credit, liquidity, market, and interest-rate risks. The general condition of the financial markets and the economy may increase those risks and may affect the value and liquidity of investments and restrict our ability to access the capital markets. Marketable debt securities with remaining maturities of 12 months or less are classified as short-term and marketable securities with remaining maturities greater than 12 months are classified as long-term. All marketable debt securities are reported at fair value and any unrealized gains and losses are reported as a component of *accumulated other comprehensive income,* on the consolidated statement of stockholders' deficit, with the exception of unrealized losses believed to be other-than-temporary, which are recorded in *interest and investment income (loss, net*, on the consolidated statement of operations. Realized gains and losses from sales of securities and the amounts, net of tax, reclassified out of *accumulated other comprehensive income*, if any, are determined on a specific identification basis.

Marketable Equity Securities

Investments in mutual funds and equity securities, other than equity method investments, are recorded at fair market value, if fair value is readily determinable and any unrealized gains and losses are included in *other income (expense, net,* on the consolidated statement of operations. Realized gains and losses from the sale of the securities are determined on a specific identification basis and the amounts are included in *other income (expense, net,* on the consolidated statement of operations.

Evaluating Investments for Other-than-Temporary Impairments

We periodically evaluate whether declines in fair values of our investments below their book value are other-than-temporary. This evaluation consists of several qualitative and quantitative factors regarding the severity and duration of the unrealized loss, as well as our ability and intent to hold the investment until a forecasted recovery occurs. Additionally, we assess whether we have plans to sell the security or whether it is more likely than not we will be required to sell any investment before recovery of its amortized cost basis. Factors considered include quoted market prices, recent financial results and operating trends, implied values from any recent transactions or offers of investee securities, credit quality of debt instrument issuers, other publicly available information that may affect the value of our investments, duration and severity of the decline in value, and our strategy and intentions for holding the investment. There were no other-than-temporary impairments recorded during the years ended December 31, 2024, 2023 and 2022.

Equity Method of Accounting

In circumstances where we have the ability to exercise significant influence over the operating and financial policies of a company in which we have an investment, we utilize the equity method of accounting for recording investment activity. In assessing whether we exercise significant influence, we consider the nature and magnitude of our investment, the voting and protective rights we hold, any participation in the governance of the other company and other relevant factors such as the presence of a collaborative or other business relationship. Under the equity method of accounting, we record our share of the income or loss of the other company as *loss on equity method investment*, on the consolidated statement of operations.

Property, Plant and Equipment, Net

Property, plant and equipment are stated at historical cost less accumulated depreciation. Historical cost includes expenditures that are directly attributable to the acquisition of the items. All repairs and maintenance are charged to operating expenses during the financial period in which they are incurred. Depreciation of property, plant and equipment is calculated using the straight-line method over the estimated useful lives of the assets, as follows:

Buildings	39 years
Software	3 years
Laboratory equipment	5 to 7 years
Furniture & fixtures	5 years
IT equipment	3 years
Leasehold improvements	The lesser of the lease term or life of the asset

Upon disposal of property, plant and equipment, the cost and related accumulated depreciation are removed from the consolidated financial statements and the net amount, less any proceeds, is included in *other income (expense), net*, on the consolidated statement of operations.

We review impairment of property, plant and equipment for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability is measured by a comparison of the carrying amount to the future net cash flows that the assets are expected to generate. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the projected undiscounted future cash flows arising from the assets using a discount rate determined by management to be commensurate with the risk inherent to our current business model.

Asset Acquisitions and Business Combinations

We make certain judgments to determine whether transactions should be accounted for as acquisitions of assets or as business combinations. If it is determined that substantially all of the fair value of gross assets acquired in a transaction is concentrated in a single asset (or a group of similar assets), the transaction is treated as an acquisition of assets. We evaluate the inputs, processes, and outputs associated with the acquired set of activities and assets. If the assets in a transaction include an input and a substantive process that together significantly contribute to the ability to create outputs, the transaction is treated as an acquisition of a business.

In transactions accounted for as asset acquisitions, the cost of an asset acquisition, including transaction costs, are allocated to identifiable assets acquired and liabilities assumed based on a relative fair value basis. Goodwill is not recognized in an asset acquisition. Any difference between the cost of an asset acquisition and the fair value of the net assets acquired is allocated to the non-monetary identifiable assets based on their relative fair values. In an asset acquisition, upfront payments allocated to in-process research and development projects at the acquisition date are expensed unless there is an alternative future use. In addition, product development milestones are expensed upon achievement. Any contingent consideration, such as payments upon achievement of various developmental, regulatory, and commercial milestones, generally is not recognized at the acquisition date.

Business combinations are accounted for using the acquisition method of accounting, which requires that assets acquired and liabilities assumed generally be recorded at their fair values as of the acquisition date. Excess of consideration over the fair value of net assets acquired is recorded as goodwill. Estimating fair value requires us to make significant judgments and assumptions. We perform impairment testing of goodwill annually or more frequently if events or changes in circumstances indicate that it is more likely than not that the asset is impaired. Acquisition costs related to a business combination are expensed as incurred.

Contingent consideration incurred in connection with a business combination are recorded at their fair values on the acquisition date and re-measured at their fair values each subsequent reporting period until the related contingencies are resolved. The resulting changes in fair value are recorded as research and development expense, on the consolidated statements of operations and comprehensive loss. Changes in fair value reflect changes to our assumptions regarding probabilities of successful achievement of related milestones, the timing in which the milestones are expected to be achieved, and the discount rate used to estimate the fair value of the obligation.

Common Control Transactions

Transactions between us and entities where Dr. Soon-Shiong and his affiliates are the controlling stockholders are accounted for as common control transactions whereby the net assets acquired or transferred are accounted at their carrying value. Any difference between the carrying value and consideration recognized is treated as a capital transaction. Cash consideration up to the carrying value of the net assets acquired or transferred is presented as an investing activity on the consolidated statement of cash flows. Cash consideration in excess of the carrying value of the net assets acquired or transferred is presented as a financing activity on the consolidated statement of cash flows.

Intangible Assets, Net

Intangible assets acquired in a business combination or an asset acquisition are initially recognized at their fair value on the acquisition date. Acquired indefinite-lived assets, such as IPR&D acquired in a business combination, are not amortized until they become definite-lived assets, upon the successful completion of the associated research and development effort. At that time, we evaluate whether the recorded amounts are impaired and make any necessary adjustments and then determine the useful life of the asset and begin amortization. If the associated research and development effort is abandoned, the related IPR&D assets is written-off and an impairment charge recorded. IPR&D acquired in an asset acquisition is expensed immediately.

Acquired definite-lived intangible assets are amortized using the straight-line method over their respective estimated useful lives. The amortization of these intangible assets is included in *selling, general and administrative expense,* on the consolidated statement of operations. Intangible assets are tested for impairment at least annually or more frequently if indicators of potential impairment exist.

Patents

Patent costs, including related legal costs, are expensed as incurred and recorded in *selling, general and administrative expense,* on the consolidated statement of operations.

Cloud Computing Arrangement

The company capitalizes implementation costs under a cloud computing arrangement that is a service contract in line with its policy for internal-use software. Costs incurred during the application development stage related to the implementation of the hosting arrangement are capitalized and included in *prepaid expenses and other current assets* and *other assets,* on the consolidated balance sheet. Amortization of capitalized implementation costs is recognized on a straight-line basis over the shorter of the estimated useful life or the terms of the underlying hosting arrangement when it is ready for its intended use. Costs related to preliminary project activities and post-implementation activities are expensed as incurred.

Fair Value Measurements

Fair value is defined as an exit price that would be received from the sale of an asset or paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. We use a three-tier fair value hierarchy to classify and disclose all assets and liabilities measured at fair value on a recurring basis, as well as assets and liabilities measured at fair value on a non-recurring basis, in periods subsequent to their initial measurement. The hierarchy requires us to use observable inputs when available, and to minimize the use of unobservable inputs, when determining fair value.

The three tiers are defined as follows:

- Level 1—Observable inputs that reflect quoted market prices (unadjusted) for identical assets or liabilities in active markets at the measurement date. Since valuations are based on quoted prices that are readily and regularly available in an active market, the valuation of these products does not entail a significant degree of judgment. Our Level 1 assets consist of bank deposits, money market funds, and marketable equity securities.

- Level 2—Observable inputs other than quoted prices in active markets that are observable either directly or indirectly in the marketplace for identical or similar assets and liabilities. Our Level 2 assets consist of corporate debt securities including commercial paper, government-sponsored securities, and corporate bonds, as well as foreign municipal securities.
- Level 3—Valuations based on inputs that are unobservable and significant to the overall fair value measurement.

We utilize a third-party pricing service to assist in obtaining fair value pricing for our investments in marketable debt securities. Inputs are documented in accordance with the fair value disclosure hierarchy. The fair values of financial instruments other than marketable securities and cash and cash equivalents are determined through a combination of management estimates and third-party valuations.

During the years ended December 31, 2024, 2023 and 2022, no transfers were made into or out of the Level 1, 2 or 3 categories. We will continue to review the fair value inputs on a quarterly basis.

Collaboration Arrangements

We analyze our collaboration arrangements to assess whether they are within the scope of FASB ASC Topic 808, *Collaborative Arrangements* (ASC 808). A collaborative arrangement is a contractual arrangement that involves joint operating activity. These arrangements involve two or more parties who are active participants in the activity and are exposed to significant risks and rewards dependent on the commercial success of the activity. This assessment is performed throughout the life of the arrangement based on changes in the responsibilities of all parties in the arrangement. To the extent the collaboration agreement is within the scope of ASC 808, we also assess whether the arrangement contains multiple elements that are within the scope of other accounting literature. If we conclude that some or all aspects of the agreement are distinct and represent a transaction with a customer, we account for those aspects of the arrangement within the scope of ASC 606. Amounts that are owed by collaboration partners within the scope of ASC 808 are recognized as an offset to research and development expense as such amounts are incurred by the collaboration partner. The amounts owed to a collaboration partner are classified as research and development expense.

Our collaboration arrangements require us to acquire certain equipment for exclusive use in the joint operating activities. These equipment purchases do not have an alternative use and are therefore expensed as incurred within research and development expense.

Our collaboration arrangements are further discussed in Note 8 *"Collaboration and License Agreements and Acquisition."*

Preclinical and Clinical Trial Accruals

As part of the process of preparing the consolidated financial statements, we are required to estimate expenses resulting from obligations under contracts with vendors, clinical research organizations and consultants. The financial terms of these contracts vary and may result in payment flows that do not match the periods over which materials or services are provided under such contracts.

We estimate clinical trial and research agreement-related expenses based on the services performed, pursuant to contracts with research institutions and clinical research organizations and other vendors that conduct clinical trials and research on our behalf. In accruing clinical and research-related fees, we estimate the time period over which services will be performed and activity expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, we will adjust the accrual accordingly. Payments made under these arrangements in advance of the receipt of the related services are recorded as prepaid expenses until the services are rendered.

Transactions with Related Parties

As outlined in Note 12 *"Related-Party Debt"* and Note 13 *"Related-Party Agreements,"* we have various agreements with related parties. These arrangements can be billed and settled in cash monthly, billed quarterly and settled in cash the following month, or estimated in advance and collected or paid upfront based on expected utilization. Monthly accruals are made for all quarterly billing arrangements.

Lease Obligations

For all leases other than short-term leases, at the lease commencement date, a right-of-use asset and a lease liability are recognized. The right-of-use asset represents the right to use the leased asset for the lease term. At the commencement date, lease right-of-use assets and lease liabilities are determined based on the present value of lease payments to be made over the lease term. Leases are classified as either finance leases or operating leases.

As the rate implicit in lease contracts are not readily determinable, we utilize its incremental borrowing rate as a discount rate for purposes of determining the present value of lease payments, which is based on the estimated interest rate at which we could borrow on a collateralized basis the amount of the lease payments in the same currency, for a similar term, in a similar economic environment. Prospectively, we will remeasure the lease liability at the net present value of the remaining lease payments using the same incremental borrowing rate that was in effect as of the lease commencement or transition date.

Operating lease right-of-use assets also include any rent paid prior to the commencement date, less any lease incentives received, and initial direct costs incurred. Lease expense for minimum lease payments is recognized on a straight-line basis over the lease term. We determine the lease term by assuming the exercise of renewal options that are reasonably assured. The exercise of lease renewal options is at our sole discretion.

We combine our lease components (e.g., fixed payments including rent, real estate taxes and insurance costs) with non-lease components (e.g., common-area maintenance costs and equipment maintenance costs) and as such, we account for lease and non-lease components as a single component. Lease expense also includes amounts relating to variable lease payments. Variable lease payments include amounts relating to common area maintenance and real estate taxes.

We do not recognize right-of-use assets and lease liabilities for qualifying short-term leases with an initial lease term of 12 months or less at lease inception. Such leases are expensed on a straight-line basis over the lease term. The lease term includes the non-cancellable period of the lease and any additional periods covered by either options to renew or not to terminate when the company is reasonably certain to exercise.

The depreciable life of operating right-of-use-assets and leasehold improvements is limited by the expected lease term.

Warrants

The company accounts for warrants as either equity-classified or liability-classified instruments based on an assessment of the warrant's specific terms and applicable authoritative guidance in ASC 480 and ASC 815. The assessment considers whether the warrants are freestanding financial instruments pursuant to ASC 480, meet the definition of a liability pursuant to ASC 480, and whether the warrants meet all of the requirements for equity classification under ASC 815, including whether the warrants are indexed to the company's own stock and whether the warrant holders could potentially require "net cash settlement" in a circumstance outside of the company's control, among other conditions for equity classification. This assessment, which requires the use of professional judgment, is conducted at the time of warrant issuance and as of each subsequent quarterly period end date while the warrants are outstanding.

For warrants that meet all criteria for equity classification, the warrants are required to be recorded as a component of *additional paid-in capital,* on the consolidated statement of stockholders' deficit at the time of issuance. For warrants that do not meet all the criteria for equity classification, the warrants are required to be recorded at their initial fair value on the date of issuance, and on each balance sheet date thereafter. Changes in the estimated fair value of the warrants are recorded as a non-cash gain or loss in *other income (expense), net*, on the consolidated statement of operations. The fair value of the warrants was estimated using the Black-Scholes option pricing model.

Fair Value Option Election

The company elected to apply the FVO method of accounting in accordance with ASC 825 and accounts for certain of its notes and embedded derivatives at fair value as a single instrument in accordance with ASC 815. The notes for which the FVO is elected are recorded at fair value upon the date of issuance and subsequently remeasured to fair value at each reporting period. Changes in the fair value of the notes accounted for at fair value are recorded as a component of *other income (expense), net,* on the consolidated statement of operations. Any changes in fair value caused by instrument-specific credit risk are recorded separately in *other comprehensive income (loss),* on the consolidated statement of comprehensive loss. The cumulative amount previously recorded in *other comprehensive income (loss)* resulting from changes in the instrument-specific credit risk for extinguished notes are reclassified and reported in current earnings on the consolidated statement of operations. All costs associated with the issuance of the convertible promissory note accounted for using the FVO were expensed upon issuance.

The company has applied the FVO on the $505.0 million December 2024 Promissory Note and $30.0 million March 2023 Promissory Note prior to its extinguishment on December 29, 2023. During the year ended December 31, 2024, the company recorded $1.2 million of changes in fair value related to instrument-specific credit risk. See Note 12 *"Related-Party Debt"* for more information.

Debt Modification and Extinguishment

The company evaluates amendments to its debt instruments in accordance with ASC 470-50. This evaluation includes comparing (1) if applicable, the net present value of future cash flows of the amended debt to that of the original debt and (2) the change in fair value of an embedded conversion feature to that of the carrying amount of the debt immediately prior to amendment to determine, in each case, if a change greater than 10% occurred. In instances where the net present value of future cash flows or the fair value of an embedded conversion feature, if any, changed more than 10%, the company applies extinguishment accounting. In instances where the net present value of future cash flows and the fair value of an embedded conversion feature, if any, changed less than 10%, the company accounts for the amendment to the debt as a debt modification. Gains and losses on debt amendments that are considered extinguishments are recognized in current earnings or in *additional paid-in capital* if the transactions are with entities under common control. Debt amendments that are considered debt modifications are accounted for prospectively through yield adjustments, based on the revised terms. Legal fees and other costs incurred with third parties that are directly related to debt modifications are expensed as incurred. Amounts paid by the company to the lenders, are reflected as additional debt discount and amortized as an adjustment of interest expense over remaining term of modified debt using the effective interest rate method.

Income Taxes

We recognize deferred tax assets and liabilities for the expected future tax consequences of temporary differences between the financial reporting and tax basis of assets and liabilities, as well as for operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using the tax rates that are expected to apply to taxable income for the years in which those tax assets and liabilities are expected to be realized or settled. We record valuation allowances to reduce deferred tax assets to the amount we believe is more likely than not to be realized.

We recognize uncertain tax positions when the position will more likely than not be upheld on examination by the taxing authorities based solely upon the technical merits of the positions. We recognize interest and penalties, if any, related to unrecognized income tax uncertainties in *income tax benefit (expense),* on the consolidated statement of operations. We did not have any accrued interest or penalties associated with uncertain tax positions as of December 31, 2024 and 2023.

Stock Repurchases

In 2015, the Board of Directors approved the 2015 Share Repurchase Program. As it is our intent for the repurchased shares to be retired, we have elected to account for the shares repurchased using the constructive retirement method. For shares repurchased in excess of par, we record the purchase price in excess of par value in *accumulated deficit*, on the consolidated balance sheet.

Revenue Interest Liability

On December 29, 2023, we entered into the RIPA with Infinity and Oberland. Pursuant to the RIPA, Oberland acquired certain Revenue Interests (as defined in the RIPA) from us for a gross purchase price of $200.0 million paid on closing and acquired additional Revenue Interests from us for a gross purchase price of $100.0 million paid on May 13, 2024. Under the

RIPA, Oberland has the right to receive quarterly payments from us based on, among other things, a certain percentage of our worldwide net sales, excluding those in China, during such quarter. The RIPA is considered a sale of future revenues and is accounted for as a liability net of a debt discount comprised of deferred issuance costs, the fair value of a freestanding option agreement related to the SPOA, and the fair value of embedded derivatives requiring bifurcation on the consolidated balance sheet. The company imputes interest expense associated with this liability using the effective interest rate method. The effective interest rate is calculated based on the rate that would enable the debt to be repaid in full over the anticipated life of the arrangement. Interest expense is recognized over the estimated term on the consolidated statement of operations. The interest rate on this liability may vary during the term of the agreement depending on a number of factors, including the level of actual and forecasted net sales. The company evaluates the interest rate quarterly based on actual and forecasted net sales utilizing the prospective method. A significant increase or decrease in actual or forecasted net sales will materially impact the revenue interest liability, interest expense, and the time period for repayment.

Derivative Liabilities

Embedded derivatives that are required to be bifurcated from the underlying debt instrument that do not meet the derivative scope exception and equity classification criteria are accounted for and valued as separate financial instruments. The terms of an embedded derivative related to a contingent exercisable prepayment feature of a convertible note have been evaluated and deemed to require bifurcation. This embedded derivative was initially measured at fair value and is remeasured to fair value at each reporting date until the derivative is settled. On December 10, 2024, the company and Nant Capital entered into a second amended and restated promissory note (the $505.0 million December 2024 Promissory Note) for which the FVO method of accounting was elected. As such, the bifurcation of the embedded derivative is not required. The embedded derivative is now included within the fair value of the second amended and restated promissory note recorded within *related-party convertible note payable at fair value*, on the consolidated balance sheet.

In addition, the RIPA contains certain features that meet the definition of being an embedded derivative requiring bifurcation as a separate compound financial instrument apart from the RIPA. The derivative liability is initially measured at fair value upon issuance and is subject to remeasurement at each reporting period with changes in fair value recognized in *other income (expense), net*, on the consolidated statement of operations.

Research and Development Costs

Major components of research and development costs include cash compensation and other personnel-related expenses, stock-based compensation, depreciation and amortization expense on research and development property and equipment and intangible assets, costs of preclinical studies, clinical trials costs, including CROs and related clinical manufacturing, including third-party CMOs, costs of drug development, costs of materials and supplies, facilities cost, overhead costs, regulatory and compliance costs, and fees paid to consultants and other entities that conduct certain research and development activities on our behalf. Costs incurred in research and development are expensed as incurred.

The company classifies its research and development expenses as either external or internal. The company’s external research and development expenses support its various preclinical and clinical programs. The company’s internal research and development expenses include payroll and benefits expenses, facilities and equipment expense, and other indirect research and development expenses incurred in support of its research and development activities. The company’s external and internal resources are not directly tied to any one research or drug discovery program and are typically deployed across multiple programs and are not allocated to specific product candidates or development programs.

Included in research and development costs are clinical trial and research expenses based on the services performed pursuant to contracts with research institutions and clinical research organizations and other vendors that conduct clinical trials and research on our behalf. We record accruals for estimated costs under these contracts. When evaluating the adequacy of the accrued liabilities, we analyze the progress of the preclinical studies or clinical trials, including the phase or completion of events, invoices received, contracted costs and purchase orders. Significant judgments and estimates are made in determining the accrued balances at the end of any reporting period based on the facts and circumstances known at that time. Although we do not expect the estimates to be materially different from the amounts actually incurred, if the estimates of the status and timing of services performed differ from the actual status and timing of services performed, we may report amounts that are too high or too low in any particular period. Actual results could differ from our estimates. We adjust the accruals in the period when actual costs become known.

Stock-Based Compensation

We account for stock-based compensation under the provisions of ASC 718. We estimate fair value of each stock option award on the date of grant using the Black-Scholes option pricing model. The Black-Scholes option pricing model requires the use of subjective assumptions, including, but not limited to, expected stock price volatility over the term of the awards and the expected term of the stock options. We measure the fair value of an equity-classified award at the grant date and recognize the stock-based compensation expense over the period of vesting on the straight-line basis for our outstanding share awards that do not contain a performance condition. For awards subject to performance-based vesting conditions, we assess the probability of the individual milestones under the award being achieved and stock-based compensation expense is recognized over the service period using the graded vesting method once management believes the performance criteria is probable of being met. For awards with service or performance conditions, we recognize the effect of forfeitures in compensation cost in the period that the award was forfeited. See Note 16 *"Stock-Based Compensation"* for more information.

Comprehensive Loss

Comprehensive loss is defined as the change in equity of a business enterprise during a period from transactions and other events and circumstances from non-owner sources. Comprehensive income or loss is composed of net (loss) income and other comprehensive (loss) income. Our other comprehensive income or loss consists of net unrealized gains (losses) on marketable debt securities classified as available-for-sale, the change in fair value of convertible note resulting from a change in the instrument-specific credit risk, net of income taxes and foreign currency translation adjustments.

Noncontrolling Interests

Noncontrolling interests are recorded for the entities that we consolidate but are not wholly-owned by the company. Noncontrolling interests are classified as a separate component of equity on the consolidated balance sheet and consolidated statement of stockholders' deficit. Additionally, net loss attributable to noncontrolling interests is reflected separately from consolidated net loss on the consolidated statement of operations and the consolidated statement of stockholders' deficit. We record the noncontrolling interests' share of loss based on the percentage of ownership interest retained by the respective noncontrolling interest holders. Noncontrolling interests recorded on the consolidated financial statements result from the company's share of GlobeImmune, of which we controlled 69.1% as of December 31, 2024, 2023 and 2022, respectively, and NANTibody, of which we controlled 100.0% as of December 31, 2024 and 2023, and 60.0% as of December 31, 2022, respectively. Noncontrolling interest stockholders are common stockholders.

GlobeImmune was determined to be a VIE as it does not have sufficient equity investment at risk to finance its operations without additional subordinated financial support and we are deemed the primary beneficiary of GlobeImmune and, accordingly, consolidate GlobeImmune into the company's consolidated financial statements under the VIE model. The company also supports GlobeImmune through a promissory note agreement, in which the company provides advances to GlobeImmune from time to time up to $6.0 million with a per annum interest rate of five percent (5%). As of December 31, 2024 and 2023, there were no outstanding advances due from GlobeImmune under the promissory note agreement.

During the years ended December 31, 2024, 2023, and 2022, GlobeImmune recognized no revenue and recognized operating expenses of $0.3 million during the years ended December 31, 2024 and 2023, and $0.5 million during the year ended December 31, 2022. As of both December 31, 2024 and 2023, the consolidated balance sheets included approximately $1.4 million of total assets that can only be used to settle obligations of GlobeImmune, and immaterial liabilities, respectively, related to GlobeImmune. The creditors of GlobeImmune do not have recourse to the general credit of the primary beneficiary.

Foreign Currencies

We have operations and hold assets in Italy and South Korea. The functional currency of the subsidiary in Italy is the Euro, based on the nature of the transactions occurring within this entity, and accordingly, assets and liabilities of this subsidiary are translated into U.S. dollars at exchange rates prevailing as of the balance sheet dates, while the operating results are translated into U.S. dollars using the average exchange rates for the period correlating with those operating results. Adjustments resulting from translating the financial statements of the foreign subsidiary into U.S. dollars are recorded as a component of *other comprehensive (loss income*, on the consolidated statement of comprehensive loss. Transaction gains and losses are recorded in *other income (expense, net,* on the consolidated statement of operations.

Basic and Diluted Net Loss per Share of Common Stock

Basic net loss per share is calculated by dividing the net loss attributable to ImmunityBio common stockholders by the weighted-average number of common shares outstanding for the period. Diluted loss per share is computed by dividing net loss attributable to ImmunityBio common stockholders by the weighted-average number of common shares, including the number of additional shares that would have been outstanding if the potential common shares had been issued and if the additional common shares were dilutive.

The following table reflects the calculation of basic and diluted loss per common share (in thousands, except per share data):

	Year Ended December 31,		
	2024	2023	2022
Net loss per ImmunityBio common share – basic			
Numerator:			
Net loss attributable to ImmunityBio common stockholders	$ (413,564)	$ (583,196)	$ (416,567)
Denominator:			
Weighted-average number of common shares outstanding – basic	697,312	508,636	399,900
Net loss per ImmunityBio common share – basic	$ (0.59)	$ (1.15)	$ (1.04)
Net loss per ImmunityBio common share – diluted			
Numerator:			
Net loss	$ (413,645)	$ (583,852)	$ (417,320)
Less: Net loss attributable to noncontrolling interests, net of tax	(81)	(656)	(753)
Add: Decrease in fair value of warrant liabilities	(19,921)	—	—
Numerator for net loss per ImmunityBio common share – diluted	$ (433,485)	$ (583,196)	$ (416,567)
Denominator:			
Weighted-average number of common shares outstanding – basic	697,312	508,636	399,900
Add: Dilutive effect of assumed exercise of "in-the-money" third-party warrants	3,131	—	—
Denominator for net loss per ImmunityBio common share – diluted	700,443	508,636	399,900
Net loss per ImmunityBio common share – diluted	$ (0.62)	$ (1.15)	$ (1.04)

Potentially dilutive securities, whose effect would have been antidilutive, were excluded from the computation of diluted net loss per share. The following table details the number of shares of common stock underlying those securities that were excluded from the computation of weighted-average number of common shares outstanding – diluted (shares in thousands):

	As of December 31,		
	2024	2023	2022
Related-party convertible notes	93,053	162,472	46,275
Outstanding stock options	15,408	9,820	9,263
Outstanding RSUs	5,945	7,504	6,551
Outstanding related-party warrants	1,638	1,638	1,638
Outstanding third-party warrants	—	37,733	9,091
Total	116,044	219,167	72,818

The potentially dilutive securities shown in the table above exclude an option to purchase up to approximately $5.0 million of the company's common stock pursuant to the SPOA entered in connection with the RIPA, as the exercise price cannot be determined until the date of exercise. See Note 15 *"Stockholders' Deficit"* for more information.

Recent Accounting Pronouncements

Application of New or Revised Accounting Standards – Adopted

In June 2022, the FASB issued ASU 2022-03*, Fair Value Measurement of Equity Securities Subject to Contractual Sale Restrictions*, which clarifies that a contractual restriction on the sale of an equity security is not considered part of the unit of account of the equity security and, therefore, is not considered in measuring fair value. This ASU also clarifies that an entity cannot, as a separate unit of account, recognize and measure a contractual sale restriction and introduces certain disclosure requirements for equity securities subject to such restrictions. We adopted this ASU on January 1, 2024 on a prospective basis with no impact on our consolidated financial statements.

In March 2023, the FASB issued ASU 2023-01, *Leases – Common Control Arrangements (Topic 842*. This ASU provides updated guidance for accounting for leasehold improvements associated with common control leases. We adopted this ASU on January 1, 2024 on a prospective basis with no impact on our consolidated financial statements.

In November 2023, the FASB issued ASU 2023-07, *Segment Reporting (Topic 280: Improvements to Reportable Segment Disclosures*, which requires disclosure of incremental segment information on an annual and interim basis. This ASU is effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024 on a retrospective basis. We adopted this ASU on December 31, 2024 on a retrospective basis. See Note 19 *"Segment and Geographic Information"* for more information.

Application of New or Revised Accounting Standards – Not Yet Adopted

In August 2023, the FASB issued ASU 2023-05, *Business Combinations-Joint Venture Formations (Subtopic 805-60: Recognition and Initial Measurement*, which requires a joint venture to initially measure all contributions received upon its formation at fair value. This ASU is applicable to joint venture entities with a formation date on or after January 1, 2025 on a prospective basis. We will apply this guidance prospectively in future reporting periods after the guidance is effective to any future arrangements meeting the definition of a joint venture.

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740: Improvements to Income Tax Disclosures*, to improve its income tax disclosure requirements. Under this ASU, entities must annually (1) disclose specific categories in the rate reconciliation, (2) provide additional information for reconciling items that meet a quantitative threshold, and (3) disclose more detailed information about income taxes paid, including by jurisdiction; pretax income (or loss) from continuing operations; and income tax expense (or benefit). This ASU is effective for fiscal years beginning after December 15, 2024, with early adoption permitted. We are currently evaluating the impact of this standard on our disclosures.

In November 2024, the FASB issued ASU 2024-03, *Expense Disaggregation Disclosures (Subtopic 220-40: Disaggregation of Income Statement Expenses*, which requires that public business entities disclose additional information about specific expense categories in the notes to financial statements at interim and annual reporting periods. This ASU is effective for fiscal years beginning after December 15, 2026, and interim periods within fiscal years beginning after December 15, 2027. This ASU may be applied either on a prospective or retrospective basis. We are currently evaluating the impact of this standard on our disclosures.

In November 2024, the FASB issued ASU 2024-04, *Debt-Debt with Conversion and Other Options (Subtopic 470-20: Induced Conversions of Convertible Debt Instruments*, which clarifies the requirements for determining whether certain settlements of convertible debt instruments should be accounted for as an induced conversion. This ASU is effective for fiscal years beginning after December 15, 2025 and interim reporting periods within those annual reporting periods, with early adoption permitted. We are currently evaluating the impact of this standard on our disclosures.

Other recent authoritative guidance issued by the FASB (including technical corrections to the ASC) and the SEC during the year ended December 31, 2024 did not, or are not expected to, have a material effect on our consolidated financial statements.

3. Revenues

As discussed in Note 2 *"Summary of Significant Accounting Policies,"* revenues are recognized in accordance with ASC 606. The following table presents our disaggregated revenue for the periods presented (in thousands):

	Year Ended December 31,		
	2024	2023	2022
Product revenue, net	$ 14,150	$ —	$ —
Other revenues	595	622	240
Total revenue	$ 14,745	$ 622	$ 240

Product Revenue, Net

During the year ended December 31, 2024, our only source of product revenue has been from U.S. sales of ANKTIVA, which we began shipping to customers in May 2024.

During the year ended December 31, 2024, approximately $1.6 million of gross-to-net adjustments have been recorded as a reduction of revenue on the consolidated statement of operations. As of December 31, 2024, approximately $0.2 million of allowances for prompt payment discounts, product returns and chargebacks were included in *accounts receivable, net,* and approximately $0.5 million related to accrued rebates, distributor fees and co-payment assistance were included in *accrued expenses and other current liabilities,* on the consolidated balance sheet.

Other Revenues

During the years ended December 31, 2024, 2023 and 2022, our primary sources of other revenues were bioreactors and related consumable product sales.

4. Inventories

Inventories consist of the following (in thousands):

	As of December 31,	
	2024	2023
Raw materials	$ —	$ —
Work-in-progress	7,505	—
Finished goods	767	—
Inventories	$ 8,272	$ —

We began capitalizing inventory costs associated with ANKTIVA after receiving FDA approval in April 2024 when it was determined that the inventory had a probable future economic benefit.

Inventory is stated at the lower of cost or net realizable value and consists of raw materials, work-in-progress and finished goods. Cost is determined using a standard cost method, which approximates actual cost, and assumes a FIFO flow of goods. Inventory that is used for clinical development purposes is expensed in *research and development expense*, on the consolidated statement of operations when consumed.

Cost of sales consists primarily of third-party manufacturing costs, distribution, and overhead costs related to sales of approved product subsequent to receiving regulatory approval. Cost of sales may also include costs related to excess or obsolete inventory adjustment charges, abnormal costs, unabsorbed manufacturing and overhead costs, and manufacturing variances. All costs associated with the production of ANKTIVA prior to receiving regulatory approval were expensed in *research and development expense*, on the consolidated statement of operations in the period incurred and therefore are not reflected in cost of sales.

The work-in-progress materials consists of bulk drug substance and drug product, which have a multi-year shelf life. When the bulk drug substance is manufactured into ANKTIVA drug product, those goods have a shelf life of two years from the date of manufacture. During September 2024, the shelf life of ANKTIVA drug product was extended to three years. The work-in-progress drug product gets converted to finished goods at the time of labeling. Our expectation is to sell finished goods at least twelve months prior to expiration. Due to our long manufacturing lead time, it was necessary to build up inventory in support of ANKTIVA forecasted sales. As a result of being in the early stages of the ANKTIVA product launch, the company is continuing to evaluate the length of its operating cycle.

On a quarterly basis, the company analyzes its inventory levels for excess quantities and obsolescence (expiration), taking into account factors such as historical and anticipated future sales compared to quantities on hand and the remaining shelf life. As of December 31, 2024, we determined that a reserve related to ANKTIVA inventory for excess quantities and obsolescence was not required. In addition, since the FDA approval of ANKTIVA the company has not recorded any inventory write downs.

5. Financial Statement Details

Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist of the following (in thousands):

	As of December 31,	
	2024	2023
Prepaid services	$ 7,762	$ 5,869
Prepaid research and development costs	5,815	7,847
Prepaid software license fees	2,687	2,100
Prepaid insurance	2,057	2,242
Prepaid rent	1,532	1,113
Prepaid equipment maintenance	1,448	1,183
Insurance premium financing asset	1,248	1,475
ERP system implementation cost	187	1,087
Insurance claims receivable	—	1,149
Other	1,116	1,538
Prepaid expenses and other current assets	$ 23,852	$ 25,603

Property, Plant and Equipment, Net

Property, plant and equipment, net, consist of the following (in thousands):

	As of December 31,	
	2024	2023
Leasehold improvements	$ 73,126	$ 72,552
Equipment	73,578	69,915
Construction in progress	86,417	84,436
Software	1,697	1,666
Furniture & fixtures	1,865	1,889
Gross property, plant and equipment	236,683	230,458
Less: Accumulated depreciation and amortization	99,589	84,376
Property, plant and equipment, net	$ 137,094	$ 146,082

During the years ended December 31, 2024, 2023 and 2022, depreciation expense related to property, plant and equipment totaled $15.5 million, $16.5 million and $16.3 million, respectively.

Goodwill and Intangible Assets, Net

The gross carrying amounts, accumulated amortization and impairment of goodwill and intangible assets, net are as follows at the dates indicated (in thousands):

	December 31, 2024				
	Weighted-Average Life (in years)	Gross Carrying Amount	Accumulated Amortization	Accumulated Impairment	Net Carrying Amount
Definite-lived: Favorable leasehold rights	7.1	$ 20,398	$ (5,864)	$ —	$ 14,534
Indefinite-lived:					
Goodwill		910	—	—	910
IPR&D		1,375	—	(886)	489
Total indefinite-lived assets		2,285	—	(886)	1,399
Goodwill and intangible assets, net		$ 22,683	$ (5,864)	$ (886)	$ 15,933

	December 31, 2023				
	Weighted-Average Life (in years)	Gross Carrying Amount	Accumulated Amortization	Accumulated Impairment	Net Carrying Amount
Definite-lived: Favorable leasehold rights	8.1	$ 20,398	$ (3,825)	$ —	$ 16,573
Indefinite-lived: IPR&D		1,406	—	(886)	520
Goodwill and intangible assets, net		$ 21,804	$ (3,825)	$ (886)	$ 17,093

Definite-Lived Intangible Assets

In connection with the acquisition of the Dunkirk Facility in 2022, we acquired definite-lived intangibles consisting of favorable leasehold rights and an organized workforce. During the year ended December 31, 2022, we wrote off the entire unamortized organized workforce intangible asset totaling $0.7 million in *impairment of intangible assets*, on the consolidated statement of operations. See Note 8 *"Collaboration and License Agreements and Acquisition"* for more information.

We recorded amortization expense of our definite-lived intangible assets of $2.0 million during the years ended December 31, 2024 and 2023, respectively, and $1.9 million, during the year ended December 31, 2022 in *research and development expense*, on the consolidated statements of operations.

Indefinite-Lived Intangible Assets

Goodwill

In September 2024, we entered into an asset purchase agreement with an unrelated party pursuant to which the company acquired the rights to hire its workforce and purchase certain office equipment in exchange for consideration of $1.0 million, net of transaction costs. The transaction was accounted for as a business combination. The fair value of the acquired identifiable net assets was $0.1 million. We recognized the remaining $0.9 million as goodwill. No goodwill impairment was recognized for the year ended December 31, 2024.

IPR&D

During the year ended December 31, 2023, we discontinued the research and development program associated with the Tarmogen platform based on results gathered from clinical data. We recorded a charge totaling $0.9 million in *impairment of intangible assets*, on the consolidated statement of operations in connection with the write down of the carrying value of

Tarmogen to zero. No such impairments were recorded during the years ended December 31, 2024 and 2022. As of December 31, 2024 and 2023, the company had indefinite-lived IPR&D intangible assets of $0.5 million, which were obtained from business acquisitions.

Future amortization expense associated with our definite-lived intangible assets, net is as follows (in thousands):

Years ending December 31:	Definite-lived Intangible Assets
2025	$ 2,040
2026	2,040
2027	2,040
2028	2,040
2029	2,040
Thereafter	4,334
Total	$ 14,534

Convertible Note Receivable

In 2016, we executed a convertible promissory note pursuant to which we advanced Riptide a principal amount of $5.0 million. The note bears interest at a per annum rate of five percent (5%). Concurrent with the transaction, we entered into an exclusive license agreement with Riptide to obtain worldwide exclusive rights, with the right to sublicense, certain know-how related to RP-182, RP-233 and RP-183. We are required to pay a single-digit royalty on net sales of the licensed products on a country-by-country basis. Pursuant to the license agreement, we are also required to make cash milestone payments upon successful completion of certain clinical, regulatory and commercial milestones up to an aggregate amount of $47.0 million for the first three indications of the licensed product with a maximum payment amount of $100.0 million.

In 2019, we entered into a first amendment to the convertible promissory note with Riptide. Under the agreement, we extended the maturity of the promissory note to the earlier of (a) the later of (i) the completion of non-clinical IND enabling studies by the company, or (ii) December 31, 2020; and (b) when we accelerate the maturity of the note upon the occurrence of an event of default. No other terms and conditions of the promissory note were modified. Concurrently, we also entered into a first amendment to the exclusive license agreement with Riptide and extended the achievement dates for certain clinical trial milestones related to the licensed products. This option for receiving a 25% discount was determined to have an immaterial value at inception and life-to-date of the note, as the probability of a future qualifying event is remote. The convertible note receivable balance was $7.1 million and $6.9 million, which included accrued interest of $2.1 million and $1.9 million as of December 31, 2024 and 2023, respectively.

Accrued Expenses and Other Liabilities

Accrued expenses and other liabilities consist of the following (in thousands):

	As of December 31,	
	2024	2023
Accrued professional and service fees	$ 16,849	$ 9,829
Accrued bonus	10,346	11,350
Accrued compensation	4,679	6,241
Accrued research and development costs	3,002	7,700
Accrued preclinical and clinical trial costs	2,876	4,218
Financing obligation – current portion	1,248	1,475
Accrued construction costs	628	1,179
Other	952	716
Accrued expenses and other liabilities	$ 40,580	$ 42,708

Interest and Investment Income (Loss), Net

Interest and investment income (loss), net consists of the following (in thousands):

	Year Ended December 31,		
	2024	2023	2022
Investment accretion income (amortization expense), net	$ 6,249	$ 1,844	$ (1,486)
Interest income	2,400	863	2,708
Unrealized losses from equity securities	(632)	(1,591)	(4,190)
Net realized (losses) gains on investments	(42)	15	(122)
Interest and investment income (loss), net	$ 7,975	$ 1,131	$ (3,090)

Interest income includes interest from marketable securities, convertible note receivable, other assets, and on bank deposits. Investment accretion income (amortization expense), net includes accretion of discounts (amortization of premiums) from securities classified as cash equivalents and marketable debt securities.

Interest expense

Interest expense consists of the following (in thousands):

	Year Ended December 31,		
	2024	2023	2022
Interest expense on related-party notes payable	$ 92,001	$ 86,453	$ 47,145
Amortization of related-party notes discounts	22,587	42,396	16,282
Other interest expense	82	85	88
Interest expense (including amounts with related parties)	$ 114,670	$ 128,934	$ 63,515

6. Financial Instruments

Investments in Marketable Debt Securities

As of December 31, 2024, the weighted-average remaining contractual life, amortized cost, gross unrealized gains, gross unrealized losses, and fair value of marketable debt securities, which were considered as available-for-sale, by type of security were as follows (in thousands):

	December 31, 2024				
	Weighted-Average Remaining Contractual Life (in years)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Current:					
U.S. Treasury securities	0.3	$ 6,094	$ 2	$ —	$ 6,096

As of December 31, 2024, no marketable debt securities were in an unrealized loss position.

As of December 31, 2023, the weighted-average remaining contractual life, amortized cost, gross unrealized gains, gross unrealized losses, and fair value of marketable debt securities, which were considered as available-for-sale, by type of security were as follows (in thousands):

	December 31, 2023				
	Weighted-Average Remaining Contractual Life (in years)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Current:					
Foreign bonds	0.8	$ 54	$ —	$ —	$ 54
Mutual funds		40	—	(1)	39
Current portion		94	—	(1)	93
Noncurrent:					
Foreign bonds	3.3	939	—	(48)	891
Total		$ 1,033	$ —	$ (49)	$ 984

Accumulated unrealized losses on marketable debt securities that have been in a continuous loss position for less than 12 months and more than 12 months as of December 31, 2023 were as follows (in thousands):

	December 31, 2023			
	Less than 12 months		More than 12 months	
	Estimated Fair Value	Gross Unrealized Losses	Estimated Fair Value	Gross Unrealized Losses
Mutual funds	$ 39	$ (1)	$ —	$ —
Foreign bonds	891	(48)	—	—
Total	$ 930	$ (49)	$ —	$ —

During the years ended December 31, 2024, 2023 and 2022, we evaluated our securities for other-than-temporary impairment and did not recognize any other-than-temporary impairment losses.

Investments in Marketable Equity Securities

As of December 31, 2024 and 2023, we held investments in marketable equity securities with readily determinable fair values of $0.3 million and $0.9 million, respectively. During the years ended December 31, 2024, 2023 and 2022, unrealized losses recorded on these securities totaled $0.6 million, $1.6 million, and $4.2 million, respectively, in *interest and investment income (loss), net*, on the consolidated statements of operations.

Investment in Other Equity Security

In August 2024, the company entered into a SAFE with an unrelated party in exchange for the right to acquire certain shares of the investee. Upon the closing of equity financing by the investee prior to the termination of the SAFE, the SAFE will convert into preferred shares. We elected to apply the measurement alternative under FASB ASC Topic 321, *Investments—Equity Securities* (ASC 321), pursuant to which we measure our investment in the SAFE at cost, less impairment. As of December 31, 2024, we recorded an investment in the SAFE of $0.7 million in *other assets*, on the consolidated balance sheet. We evaluate this investment for any indications of impairment in value on a quarterly basis. No factors indicative of impairment were identified during the year ended December 31, 2024.

7. Fair Value Measurements

Recurring Valuations

Financial assets and liabilities measured at fair value on a recurring basis are summarized below (in thousands):

	Fair Value Measurements at December 31, 2024			
	Total	Level 1	Level 2	Level 3
Assets at Fair Value:				
Current:				
Cash and cash equivalents	$ 143,428	$ 143,428	$ —	$ —
U.S. Treasury securities	6,096	6,096	—	—
Equity securities	285	285	—	—
Total assets measured at fair value	$ 149,809	$ 149,809	$ —	$ —
Liabilities at Fair Value:				
Current:				
Contingent consideration	$ (19) (1)	$ —	$ —	$ (19)
Noncurrent:				
Related-party convertible note payable at fair value (Note 12)	(461,877)	—	—	(461,877)
Derivative liabilities (Note 11)	(25,800)	—	—	(25,800)
Warrant liabilities (Note 14)	(8,575)	—	—	(8,575)
Stock option purchase liability (Note 11)	(320)	—	—	(320)
Total liabilities measured at fair value	$ (496,591)	$ —	$ —	$ (496,591)

	Fair Value Measurements at December 31, 2023			
	Total	Level 1	Level 2	Level 3
Assets at Fair Value:				
Current:				
Cash and cash equivalents	$ 265,453	$ 265,453	$ —	$ —
Equity securities	916	916	—	—
Foreign bonds	54	—	54	—
Mutual funds	39	39	—	—
Noncurrent:				
Foreign bonds	891	—	891	—
Total assets measured at fair value	$ 267,353	$ 266,408	$ 945	$ —
Liabilities at Fair Value:				
Current:				
Contingent consideration	$ (20) (1)	$ —	$ —	$ (20)
Noncurrent:				
Warrant liabilities (Note 14)	(118,770)	—	—	(118,770)
Derivative liabilities (Note 11 and Note 12)	(35,333)	—	—	(35,333)
Stock option purchase liability (Note 11)	(819)	—	—	(819)
Total liabilities measured at fair value	$ (154,942)	$ —	$ —	$ (154,942)

(1) Contingent consideration is recorded at estimated fair value and revalued each reporting period until the related contingency is resolved. The fair value measurement is based on inputs that are unobservable and significant to the overall fair value measurement (i.e., a Level 3 measurement within the fair value hierarchy) and are reviewed periodically by management. See Note 9 *"Commitments and Contingencies—Contingent Consideration Related to Business Combinations"* for more information.

Changes in the carrying amount of contingent consideration were as follows (in thousands):

	Year Ended December 31,		
	2024	2023	2022
Fair value, beginning of year	$ (20)	$ (19)	$ (409)
Consideration paid	—	—	339
Net decrease (increase) in fair value	1	(1)	51
Fair value, end of year	$ (19)	$ (20)	$ (19)

Non-Recurring Valuations

Non-financial assets and liabilities are recognized at fair value subsequent to initial recognition when they are deemed to be other-than-temporarily impaired. Except for the impairments discussed in Note 5 *"Financial Statement Details—Goodwill and Intangible Assets, Net"* there were no other material non-financial assets or liabilities deemed to be other-than-temporarily impaired and measured at fair value on a non-recurring basis during the years ended December 31, 2024, 2023 and 2022.

We measured the fair value of the promissory notes and the embedded conversion features as of December 10, 2024, December 29, 2023 and September 11, 2023, respectively, upon debt amendments to determine the accounting treatment, using a "with and without" method. We used binomial lattice models for the "with" scenario and discounted cash flow analyses for the "without" scenario. Since certain of the factors analyzed are considered to be unobservable inputs, both the lattice model and the discounted cash flow model are considered to be a Level 3 valuation. See Note 12 *"Related-Party Debt"* for more information.

8. Collaboration and License Agreements and Acquisition

Collaboration Agreements

National Cancer Institute

The company and its subsidiaries began their relationship with HHS, as represented by the NCI of the NIH in 2015. Pursuant to the CRADAs, the NCI provides scientific staff and other support necessary to conduct research and related activities as described in the CRADAs. During the term of the initial and amended CRADAs, we collaborated with the NCI on the preclinical and clinical development of our proprietary adenovirus technology expressing TAAs for cancer immunotherapy.

In 2021, the CRADA was amended and the research plan was modified to include the preclinical and clinical development of ImmunityBio's proprietary adenovirus platform expressing TAAs, proprietary agent ANKTIVA and derivatives, an antibody-based cytokine fusion protein and derivatives and/or TxM product candidates, proprietary recombinant NK cells and mAbs, proprietary adjuvants, and other proprietary agents owned or controlled by ImmunityBio for cancer immunotherapy. The term of the CRADA was extended through May 2026. Under this agreement, we agreed to pay NCI funding totaling $1.3 million per year, payable in semi-annual installments each year through 2025. During the years ended December 31, 2024 and 2023 we recorded $1.3 million, and $1.2 million during the year ended December 31, 2022 in *research and development expense,* on the consolidated statements of operations.

Pursuant to the updated CRADA research plan, NCI and ImmunityBio will collaborate on the preclinical and clinical development of ImmunityBio's proprietary adenovirus platform expressing TAAs, ANKTIVA and derivatives, an antibody-based cytokine fusion protein and derivatives and/or TxM product candidates, proprietary recombinant NK cells and mAbs, and other proprietary agents owned or controlled by ImmunityBio as contemplated in the research plan for cancer immunotherapy. Under the CRADA, any party may unilaterally terminate the agreement by providing timely advance written notice to the other party before the desired termination date. Pursuant to the terms of the CRADA, we have an option to elect to negotiate an exclusive or non-exclusive commercialization license to any inventions discovered in the performance of the CRADA. The parties jointly own any inventions and materials that are jointly produced by employees of both parties in the course of performing activities under the CRADA.

Amyris Joint Venture

In 2021, ImmunityBio and Amyris entered into a 50:50 joint venture arrangement and formed a new limited liability company to conduct the business of the joint venture. The purpose of the joint venture is to accelerate commercialization of a next-generation COVID-19 vaccine utilizing an RNA vaccine-platform. As part of the limited liability agreement, Amyris contributed $1.0 million in cash and rights to its license agreement with AAHI for an RNA platform for the field of COVID-19. ImmunityBio contributed $1.0 million in cash and priority access to its manufacturing capacity for the joint venture product. Both parties agreed to enter into a separate manufacturing and supply agreement and a sublicense agreement following the execution of the joint venture agreement.

The joint venture agreement stipulates the initial terms for equal representation in the management of the newly-formed joint venture. The joint venture is managed by a board of directors consisting of four directors: two appointed by the company and two appointed by Amyris. Both parties agreed to make additional capital contributions in cash, in proportion to their respective interests, as determined by the board of directors of the joint venture.

We considered the joint venture entity as a VIE and determined that we are not the primary beneficiary of the VIE. We account for our investment in the joint venture using the equity method of accounting. During the years ended December 31, 2023 and 2022, we recorded our 50% share of net losses from the joint venture totaling $7.5 million and $12.1 million, respectively, in *other income (expense), net*, on the consolidated statements of operations. During the years ended December 31, 2023 and 2022, such losses incurred included $7.5 million and $11.9 million, respectively, attributable to expenses incurred by us on behalf of the joint venture. We are not obligated to fund the joint venture's potential future losses. In August 2023, Amyris announced that it filed for Chapter 11 bankruptcy protection. The Amyris bankruptcy case remains ongoing, and there can be no assurance that we will receive any recovery on account of our claims against Amyris, including for Amyris' portion of expenses incurred by the joint venture. As of December 31, 2024, the carrying amount of our equity investment in the joint venture was zero.

License Agreements

3M IPC and AAHI License Agreement

We have licensed rights to 3M-052, a synthetic TLR7/8 agonist, 3M-052 formulations and related technology from 3M IPC and its affiliates and AAHI. In 2021 we obtained nonexclusive rights in the field of SARS-CoV-2 and in June 2022 we modified those rights and expanded the scope of the license to include (1) SARS-CoV-2 and other infectious diseases including malaria, HIV, tuberculosis, hookworm and varicella zoster on an exclusive basis in countries other than LMIC, and (2) oncology applications, when used in combination with our proprietary technology and/or IL-15 receptor superagonist. In consideration for the license, we agreed to make certain periodic license payments, including $2.25 million each year through June 2025. We have also agreed to make payments upon the achievement of certain regulatory milestone events and tiered royalties ranging from the low to high single-digits as a percentage of net sales. Beginning in April 2026, the annual minimum licensing payment is $1.0 million, which can be credited against any royalty payments due under this agreement.

We made annual license maintenance fee payments of $2.25 million in 2024 and 2023, and $1.75 million in 2022. During the years ended December 31, 2024, 2023 and 2022, we recorded $2.3 million, $2.0 million, and $1.0 million, respectively, in *research and development expense*, on the consolidated statements of operations.

AAHI Agreements

In 2021, ImmunityBio and AAHI entered into several agreements, including an RNA vaccine platform license agreement, an adjuvant formulation license agreement, and a sponsored research agreement (collectively, the "AAHI Agreements"). ImmunityBio is no longer pursuing development of the AAHI RNA platform and related technology it had licensed from AAHI in 2021. During the second half of 2024, the parties reached an agreement whereby ImmunityBio would owe no future payments to AAHI under the AAHI Agreements, ImmunityBio would return the licenses to AAHI, the AAHI Agreements were terminated, and each party mutually released and had no continuing obligations to the other.

With respect to the license agreements, we recorded $2.3 million, $4.5 million, and $1.8 million, respectively, in *research and development expense*, on the consolidated statements of operations during the years ended December 31, 2024, 2023 and 2022.

With respect to the sponsored research agreement, we recorded no expense and $1.2 million, respectively, in *research and development expense*, and $3.7 million in *loss on equity method investment*, on the consolidated statements of operations related to the sponsored research agreement during the years ended December 31, 2024, 2023 and 2022.

Acquisition

Dunkirk Facility Leasehold Interest

On February 14, 2022, we completed the acquisition of the Dunkirk Facility (approximately 409,000 rentable square feet) from Athenex, which we believe has the potential to provide us with a state-of-the-art biotech production center that will substantially expand and diversify our existing manufacturing capacity in the U.S. and the ability to scale production associated with certain of our product candidates. The company accounted for the transaction as an asset acquisition because the Dunkirk Facility's integrated set of assets and activities does not meet the definition of a business.

The total consideration for the acquisition was approximately $40.5 million, including a cash payment of $40.0 million, and transaction costs of approximately $0.5 million. The following table summarizes the fair value of assets acquired as of the acquisition date (in thousands):

Construction in progress	$	10,043
Leasehold improvements		6,253
Definite-lived intangible assets (1)		21,229
Other depreciable assets and prepaid expenses		2,983
Total consideration	$	40,508

(1) Definite-lived intangible assets consist of favorable leasehold rights totaling $20.4 million and organized workforce totaling $0.8 million as of the acquisition date.

Upon the closing of the Dunkirk transaction, the company became the tenant of the Dunkirk Facility under the Fort Schuyler Management Corporation Lease, dated October 1, 2021 and as amended as of the February 14, 2022 closing date (as amended, the Dunkirk Lease), with the FSMC as landlord. The Dunkirk Facility, as well as certain equipment, is owned by the FSMC and is leased to us under the Dunkirk Lease. Our annual lease payment will be $2.00 per year for an initial 10-year term, with one option to renew the lease under substantially the same terms and conditions for an additional 10-year term. As part of the transaction, we assumed certain of Athenex's obligations under various third-party agreements (the Facility Agreements), subject to the terms and conditions of the purchase agreement by and between the company and Athenex dated as of January 7, 2022, and committed to spend an aggregate of $1.52 billion on operational expenses during the initial term, and an additional $1.50 billion on operational expenses if we elect to renew the lease for one additional 10-year term. We also committed to hiring 450 employees at the Dunkirk Facility within the first five years following the Commencement Date, with 300 such employees to be hired within the first 2.5 years following the Commencement Date. We are eligible for certain sales-tax exemption savings during the development of the Dunkirk Facility, and certain property tax savings over the next 20 years, subject to certain terms and conditions, including performance of certain of the obligations described above. Failure to satisfy the obligations over the lease term may give rise to certain rights and remedies of governmental authorities including, for example, termination of the

Dunkirk Lease and other Facility Agreements and potential recoupment of a percentage of the grant funding received by Athenex for construction of the facility and other benefits received, subject to the terms and conditions of the applicable agreements. In addition, and related to the delayed completion of the facility as described above, in November 2024 we received written notice from our landlord alleging non-compliance with the initial employee headcount requirement of our lease for the Dunkirk Facility. While we are seeking to resolve this matter expeditiously, there can be no assurance that we will succeed in doing so, and we may lose access to the Dunkirk Facility.

Although we believe that governmental funding will assist in funding a portion of the further buildout of the Dunkirk Facility, which we estimate to be approximately $8.0 million to $10.0 million of governmental funding remaining available as of December 31, 2024, there can be no assurance as to the final acceptance and timing of the requests for governmental funding that we submit, and we will need to plan and fund most of the additional buildout of, and purchase additional equipment for, the Dunkirk Facility in connection with our planned full operations. In addition, any future governmental funding will be subject to the eligibility of submitted expenses, as well as our compliance with the obligations that we are subject to pursuant to the agreements with parties regarding the Dunkirk Facility as described above. Further, on May 14, 2023, Athenex, together with certain of its subsidiaries, filed voluntary petitions for relief under Chapter 11 of the United States Bankruptcy Court for the Southern District of Texas (the Athenex Proceedings). We do not know what, if any, impact the Athenex Proceedings will have on any portion of the potential governmental funding remaining for the Dunkirk Facility.

Dunkirk Facility Workforce Reduction

In 2022, the company initiated a workforce reduction at the Dunkirk Facility and recorded severance and retention benefits for the terminated employees totaling $1.0 million during the year ended December 31, 2022 in *selling, general and administrative expense,* on the consolidated statement of operations.

9. Commitments and Contingencies

Contingent Consideration Related to Business Combinations

VivaBioCell, S.p.A.

In April 2015, NantWorks, a related party, acquired a 100% interest in VivaBioCell through its wholly-owned subsidiary, VBC Holdings for $0.7 million, less working capital adjustments. In June 2015, NantWorks contributed its equity interest in VBC Holdings to the company, in exchange for cash consideration equal to its cost basis in the investment. VivaBioCell develops bioreactors and products based on cell culture and tissue engineering in Italy.

In connection with our acquisition of VBC, we are obligated to pay the former owners contingent consideration upon the achievement of certain milestones related to the GMP-in-a-Box technology. If a government agency unconditionally approves the GMP-in-a-Box technology for commercial sale (the regulatory milestone) in the future, we will be obligated to pay an additional approximately $2.1 million to the former owners.

Altor BioScience, LLC

In connection with our 2017 acquisition of Altor, we issued CVRs under which we agreed to pay the prior stockholders of Altor approximately $304.0 million of contingent consideration upon calendar-year worldwide net sales of ANKTIVA exceeding $1.0 billion prior to December 31, 2026, with amounts payable in cash or shares of our common stock or a combination thereof. As the transaction was recorded as an asset acquisition, future CVR payments will be recorded when the corresponding events are probable of achievement, or the consideration becomes payable. As of December 31, 2024, Dr. Soon-Shiong, our Founder, Executive Chairman and Global Chief Scientific and Medical Officer, and his related party hold approximately $139.8 million of net sales CVRs, and they have both irrevocably agreed to receive shares of the company's common stock in satisfaction of their CVRs. We may be required to pay the other prior Altor stockholders up to $164.2 million for their net sales CVRs should they choose to have their CVRs paid in cash instead of common stock.

Litigation

From time to time, we may be involved in various claims and legal proceedings relating to claims arising out of our operations. We are not currently a party to any legal proceedings that, in the opinion of our management, are likely to have a material adverse effect on our business. If we are served with any such complaints, we will assess at that time any contingencies for which we may need to reserve. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources, and other factors.

Altor BioScience, LLC Litigation

In 2017, NantCell announced it had entered into a definitive merger agreement to acquire Altor. An action captioned *Gray v. Soon-Shiong, et al.* was filed in the Delaware Court of Chancery by plaintiffs Clayland Boyden Gray (Gray) and Adam R. Waldman. The plaintiffs, two minority stockholders, asserted claims against the company and other defendants for (1) breach of fiduciary duty and (2) aiding and abetting breach of fiduciary duty and filed a motion to enjoin the merger. The court denied the motion and permitted the merger to close.

Subsequent to the close of the merger, in 2017 the plaintiffs (joined by two additional minority stockholders, Barbara Sturm Waldman and Douglas E. Henderson (Henderson)) filed a second amended complaint, including appraisal claims, and which the defendants subsequently moved to dismiss. In a second action, Dyad Pharmaceutical Corporation (Dyad) filed a petition in the Delaware Court of Chancery for appraisal in connection with the merger. The defendants moved to dismiss the appraisal petition in 2018. The court issued an oral ruling in 2019 that dismissed certain claims and dismissed Altor from the action. The following claims remained: (a) the appraisal claims by all plaintiffs and Dyad (against Altor BioScience, LLC), and (b) Henderson's claims for breach of fiduciary duty and aiding and abetting breach of fiduciary duty.

In 2019, the court issued a written order implementing its ruling on the defendants' motions (the Implementing Order). In the Implementing Order, the court confirmed that all fiduciary duty claims brought by Gray, both individually and as trustee of the Gordon Gray Trust f/b/o C. Boyden Gray, were dismissed. The plaintiffs then moved for leave to file a third amended complaint to add two former Altor stockholders as plaintiffs and a fiduciary duty claim on behalf of a purported class of former Altor stockholders, which the defendants opposed.

In 2020, the court granted the plaintiffs' motion, and the plaintiffs filed the third amended complaint. In 2020, the defendants answered the third amended complaint and asserted counterclaims against the plaintiffs. The defendants sought damages for attorneys' fees and costs incurred as a result of the breaches of "standstill" agreements and of stockholder releases. The plaintiffs filed an answer denying the counterclaims and asserting defenses.

The shares of the former Altor stockholders seeking appraisal met the definition of dissenting shares under the merger agreement and were not entitled to receive any portion of the merger consideration at the closing date, given that those shares were the subject of the above-described appraisal claims.

In late March 2022, the company agreed to the terms of a settlement with the appraisal petitioners, without any admission of liability or fault. The settlement provided that in exchange for complete releases, the appraisal petitioners, who as a group held 3,167,565 dissenting Altor shares, collectively would receive an aggregate of 2,229,296 shares of the company's common stock issued in a private placement, plus an aggregate of $21.13 in cash in lieu of fractional shares. The company's Board of Directors approved the settlement and stock issuance in April 2022, and the court approved the settlement and dismissed the appraisal petitioners' claims on July 9, 2022. On July 9, 2022, the company issued 2,229,296 shares of its common stock with an aggregate market value of $10.7 million, based on the closing price of its common stock on the Nasdaq as of July 8, 2022, to the appraisal petitioners pursuant to the court-approved settlement agreement.

In late April 2022, the company also agreed to the terms of a settlement with the putative class plaintiffs without any admission of liability or fault. In exchange for class-wide releases, the company committed to make a settlement payment of $5.0 million in cash by December 31, 2022. On December 8, 2022, the Delaware Court of Chancery entered a final judgment approving the settlement, and the company timely made the $5.0 million settlement payment.

Sorrento Therapeutics, Inc. Litigation

Sorrento, derivatively on behalf of NANTibody, filed an action in the Superior Court of California, Los Angeles County (the Superior Court) against the company's subsidiary NantCell, Dr. Soon-Shiong, and Charles Kim. The action alleged that the defendants improperly caused NANTibody to acquire IgDraSol from NantPharma and sought to have the transaction undone and the purchase amount returned to NANTibody. In 2019, we filed a demurrer to several causes of action alleged in the Superior Court action, and Sorrento filed an amended complaint, eliminating Mr. Kim as a defendant and dropping the causes of action we had challenged in our demurrer. Trial had been set to commence in Sorrento's Superior Court action on August 7, 2023, but on July 24, 2023 the Superior Court vacated the August 7, 2023 trial date at the parties' request in light of the pending settlement discussed below.

Also in 2019, the company and Dr. Soon-Shiong filed cross-claims in the Superior Court action against Sorrento and its Chief Executive Officer Henry Ji, asserting claims for fraud, breach of contract, breach of the covenant of good faith and fair dealing, tortious interference with contract, unjust enrichment, and declaratory relief. Our claims alleged that Dr. Ji and Sorrento breached the terms of an exclusive license agreement between the company and Sorrento related to Sorrento's antibody library and that Sorrento did not perform its obligations under the exclusive license agreement. The Superior Court ruled that the company's claims should be pursued in arbitration and that Dr. Soon-Shiong's claims could be pursued in Superior Court.

In 2019, the company, along with NANTibody, filed an arbitration against Sorrento and Dr. Ji asserting our claims relating to the exclusive license agreement. Sorrento filed counterclaims against the company and NANTibody in the arbitration. The hearings in the NANTibody arbitration commenced in April 2021 and concluded in early August 2021. After post-hearing briefing was concluded, the parties were notified on November 30, 2021 that the arbitrator in the NANTibody arbitration had passed away. A substitute arbitrator was appointed on February 25, 2022, and the parties worked with the substitute arbitrator to conclude the proceedings. Additional hearing sessions were held in May and July 2022, and summations took place on August 2, 2022.

On December 2, 2022, the arbitrator issued a final award finding that Sorrento had breached the two exclusive license agreements with NantCell and NANTibody. The arbitrator awarded NantCell approximately $156.8 million and NANTibody approximately $16.7 million, plus post-award interest accruing at a daily rate. On December 21, 2022, NantCell and NANTibody filed petitions in the Superior Court to confirm the arbitration award; on January 16, 2023, Sorrento filed a response to the petitions and moved to vacate the award. On February 7, 2023, after a hearing, the Superior Court entered orders confirming the arbitration award and denying Sorrento's motion to vacate. The Superior Court entered judgments against Sorrento in the aggregate amount of approximately $176.4 million plus 10% post-judgment interest, of which approximately $159.4 million was payable to NantCell, and the remainder of which was payable to NANTibody. On February 13, 2023, Sorrento informed counsel to the company that it had filed a Chapter 11 proceeding in the United States District Court for the Southern District of Texas, *In re: Sorrento Therapeutics, Inc., et al.,* Case No. 23-90085 (DRJ), Docket Entry 810.

On June 6, 2023, Sorrento filed a motion in its Chapter 11 proceeding for entry of an order approving and implementing a mediation settlement reached with the company and other entities. The settlement involved two possible scenarios: Either, if Sorrento were to raise an amount needed to pay its debtor in possession lender and its unsecured creditors by August 31, 2023, Sorrento would pay those obligations, including the judgments held by NantCell and NANTibody, by 2:00 p.m. ET on August 31, 2023 and be free to proceed with pending litigation; or, failing that, the judgments would be released, the litigation claims would be released, including, without limitation, the Superior Court action discussed above, Sorrento would relinquish its interests in NANTibody and certain other entities, Sorrento would forfeit its rights to any payments from NantCell arising out of its antibody exclusive license agreement with NantCell (rights to PD-L1), and certain other provisions not impacting the company would be implemented as described in the motion. On August 14, 2023, the United States Bankruptcy Court for the Southern District of Texas issued an order approving the settlement described above, such that the settlement became binding on the parties. As of 2:00 p.m. ET on August 31, 2023, Sorrento had not paid the judgments held by NantCell and NANTibody. Accordingly, in relevant part to the company and NantCell, a mutual release of claims became effective such that the aforementioned judgments were released, the litigation claims were released including, without limitation, the derivative litigation against NantCell described above, Sorrento relinquished its interests in NANTibody, and Sorrento forfeited its rights to any payments from NantCell arising out of its antibody exclusive license agreement with NantCell, including any royalties associated with the company's engineered NK cell therapy in Phase 2 clinical trials, PD-L1 t-haNK. As a result of the settlement, the parties filed dismissals of the litigation matters discussed above. After the settlement, the company's ownership in NANTibody increased from 60% to 100%, and, as a result, the carrying amount of the noncontrolling interest of $4.2 million was adjusted and recognized in *additional paid-in capital* attributable to the company, on the consolidated statement of stockholders' deficit.

Shenzhen Beike Biotechnology Co. Ltd. Arbitration

In 2020, we received a Request for Arbitration before the International Chamber of Commerce, International Court of Arbitration. The arbitration relates to a license, development, and commercialization agreement that Altor entered into with Beike in 2014, which agreement was amended and restated in 2017, pursuant to which Altor granted to Beike an exclusive license to use, research, develop and commercialize products based on ANKTIVA in China for human therapeutic uses. In the arbitration, Beike is asserting a claim for breach of contract under the license agreement. Among other things, Beike alleges that we failed to

use commercially reasonable efforts to deliver to Beike materials and data related to ANKTIVA. Beike is seeking specific performance and declaratory relief for the alleged breaches. On September 25, 2020, the parties entered into a standstill and tolling agreement (standstill agreement) under which, among other things, the parties affirmed they will perform certain of their obligations under the license agreement by specified dates and agreed that all deadlines in the arbitration are indefinitely extended. The standstill agreement could be terminated by any party on ten calendar days' notice, and upon termination, the parties had the right to pursue claims arising from the license agreement in any appropriate tribunal. On March 20, 2023, we terminated the standstill agreement, and on April 11, 2023, Beike served an amended Request for Arbitration. We served an Answer and Counterclaims on May 19, 2023. Beike served a Reply to our counterclaims on June 21, 2023. Beike served its Statement of Claim on March 22, 2024, and the company served its Statement of Defense and Counterclaim on June 21, 2024, and Beike served its Statement of Defense to the Counterclaim on August 2, 2024. After the parties completed discovery, Beike served its Reply and Defense to Counterclaim on January 17, 2025. The hearing in the arbitration is scheduled to begin on June 9, 2025. Given that the proceeding is in the pre-hearing stages, it remains too early to evaluate the likely outcome of the case or to estimate any range of potential loss. We believe the claims asserted against the company lack merit and intend to defend the case, and to pursue our counterclaims, vigorously.

Securities Class Action

On June 30, 2023, a putative securities class action complaint, captioned *Salzman v. ImmunityBio, Inc. et al.*, No. 3:23-cv-01216-GPC-VET, was filed in the United States District Court for the Southern District of California against the company and three of its officers and/or directors, asserting violations of Sections 10(b) and 20(a) of the Exchange Act. Stemming from the company's disclosure on May 11, 2023 that it had received an FDA CRL stating, among other things, that it could not approve the company's BLA for its then product candidate, ANKTIVA with BCG for the treatment of adult patients with BCG-unresponsive NMIBC with CIS with or without papillary tumors, in its present form due to deficiencies related to its pre-license inspection of the company's third-party CMOs, the complaint alleges that the defendants had previously made materially false and misleading statements and/or omitted material adverse facts regarding its third-party CMOs and the prospects for regulatory approval of the BLA. The complaint did not specify the amount of damages being sought. On September 27, 2023, the court appointed a lead plaintiff, approved their selection of lead counsel, and re-captioned the case *In re ImmunityBio, Inc. Securities Litigation,* No. 3:23-cv-01216. On November 17, 2023, the lead plaintiff filed an amended complaint, which named the same defendants and asserted the same claims as the previous complaint. On January 8, 2024, the defendants filed a motion to dismiss the amended complaint. On June 20, 2024, the court issued an order granting in part and denying in part the motion to dismiss. On July 16, 2024, the lead plaintiff notified the court that he would proceed with his current pleading, and the defendants answered the complaint on August 29, 2024. On January 25, 2025, following a mediation and the parties' agreement in principle to settle the securities class action for $10.5 million, the lead plaintiff filed an unopposed motion for preliminary approval of class action settlement. The settlement is subject to preliminary and final approval by the U.S. District Court for the Southern District of California. A preliminary approval hearing is scheduled for March 7, 2025.

As a result of the foregoing, the company recorded legal settlement expense of $10.5 million in *selling, general and administrative expense,* on the consolidated statement of operations during the year ended December 31, 2024 and a corresponding amount in *accrued expenses and other liabilities*, on the consolidated balance sheet. The company believes that approximately $6.0 million of this amount will be paid by the company's insurers, which will be recorded upon receipt.

To the extent the court does not grant final approval of the settlement described above, the company is unable to estimate a range of loss, if any, that could result were there to be an adverse final decision in this action. In this event and if an unfavorable outcome were to occur, it is possible that the impact could be material to the company's results of operations in the period(s) in which any such outcome becomes probable and estimable.

Van Luven, Barbieri and Shin Derivative Actions

On October 29, 2024, a shareholder derivative action was filed in the United States District Court for the Southern District of California against the members of our Board of Directors and certain officers, captioned *Van Luven v. Soon-Shiong et al.*, Case No. 3:24-cv-02014-GPC-VET. The plaintiff purports to bring the action derivatively on behalf of ImmunityBio, and ImmunityBio is a nominal defendant to the action. Stemming from the company's May 11, 2023 disclosure that it had received an FDA CRL stating, among other things, that it could not approve the company's BLA for its then product candidate, ANKTIVA with BCG for the treatment of adult patients with BCG-unresponsive NMIBC with CIS with or without papillary tumors, in its present form due to deficiencies related to its pre-license inspection of the company's third-party CMOs, the derivative complaint

alleges that the individual defendants authorized or permitted materially false and misleading statements and/or omitted material adverse facts regarding ImmunityBio's third-party CMOs and the prospects for regulatory approval of the ANKTIVA BLA. The derivative complaint asserts claims for violations of Section 14(a) of the Exchange Act as well as claims for breach of fiduciary duty, unjust enrichment, and waste of corporate assets. The derivative complaint seeks unspecified damages on behalf of the company, disgorgement or restitution, declaratory relief, and an award of costs and expenses to the derivative plaintiff, including attorneys' fees. The court entered an order extending the defendants' deadline to respond to the complaint to April 18, 2025.

On February 25, 2025, a second shareholder derivative action was filed in the United States District Court for the Southern District of California against certain members of our Board of Directors and certain officers, captioned *Barbieri v. Soon-Shiong, et al*., Case No. 3:25-cv-00416-AGS-JLB. The plaintiff purports to bring the action derivatively on behalf of ImmunityBio, and ImmunityBio is a nominal defendant in the action. This lawsuit asserts substantially similar claims and allegations as *Van Luven*.

On February 26, 2025, a third shareholder derivative action was filed in the United States District Court for the Southern District of California against certain current and former members of our Board of Directors and certain officers, captioned *Shin v. Soon-Shiong, et al.*, Case No. 3:25-cv-00423-JAH-DDL. The plaintiff purports to bring the action derivatively on behalf of ImmunityBio, and ImmunityBio is a nominal defendant in the action. This lawsuit asserts substantially similar claims and allegations as Van *Luven*.

Carlson Derivative Action

On November 20, 2024, a shareholder derivative action was filed in the Delaware Court of Chancery against the company's Founder, Executive Chairman, Global Chief Scientific and Medical Officer and principal stockholder, Dr. Soon-Shiong, certain affiliates of Dr. Soon-Shiong, certain other members of management, and members of the company's Board of Directors who serve on the Board of Directors' Related Party Transaction Committee, captioned *Carlson v. Soon-Shiong, et al.,* Case No. 2024-1195-VCL. The plaintiff purports to bring the action derivatively on behalf of ImmunityBio, and ImmunityBio is a nominal defendant to the action. The plaintiff alleges that the previously disclosed September 2023 financing transactions between the company and Dr. Soon-Shiong and his affiliates were not fair to the company. In particular, the plaintiff alleges that the transactions were timed to benefit Dr. Soon-Shiong and his affiliates during a temporary decline in the company's stock price, resulting in an artificially low conversion price for certain convertible promissory notes that were among the transactions, when defendants knew the company's stock price would increase following the company's imminent resubmission of a BLA for, and the subsequent FDA approval of, ANKTIVA with BCG for the treatment of adult patients with BCG-unresponsive NMIBC with CIS with or without papillary tumors. The complaint alleges that defendants breached their fiduciary duties by entering into these transactions at that time and on those terms, thereby unjustly enriching Dr. Soon-Shiong and his affiliates. The derivative complaint seeks unspecified damages on behalf of the company, corporate governance changes with respect to related-party transactions, and an award of costs and expenses to the derivative plaintiff, including attorneys' fees. On February 17, 2025, the defendants filed a motion to dismiss the complaint.

Unconditional Purchase Obligations

Unconditional purchase obligations are defined as an agreement to purchase goods or services that are enforceable and legally binding (non-cancelable, or cancellable only in certain circumstances). Estimated future minimum unconditional purchase obligations as of December 31, 2024 are as follows (in thousands):

	Years Ending December 31,				
	2025	2026	2027	2028	2029
Software license fees and installation costs	$ 2,658	$ 2,675	$ 844	$ 159	$ 106
Reserved cGMP manufacturing capacity at third-party CMO facilities	1,606	—	—	—	—
Laboratory clean room services	716	—	—	—	—
Commercial launch services	136	—	—	—	—

The purchase obligation amounts do not represent the entire anticipated purchases in the future but represent only those items for which we are contractually obligated. The majority of our goods and services are purchased as needed, with no unconditional commitment. For this reason, these amounts do not provide an indication of our expected future cash outflows related to purchases.

Commitments

During the year ended December 31, 2024, we did not enter into any significant contracts, other than those disclosed in these consolidated financial statements.

10. Lease Arrangements

We lease property in multiple facilities across the U.S. and Italy, including facilities located in El Segundo, CA and the Dunkirk Facility in upstate New York. Substantially all of our operating lease right-of-use assets and operating lease liabilities relate to facilities leases. All of our finance leases were related to equipment rental at the Dunkirk Facility. See Note 13 *"Related-Party Agreements"* for more information about our related-party leases.

Our leases generally have initial terms ranging from two to ten years and often include one or more options to renew. These renewal terms can extend the lease term from one to ten years and are included in the lease term when it is reasonably certain that we will exercise the option.

Supplemental balance sheet information related to our leases is as follows (in thousands):

		As of December 31,	
	Classification	2024	2023
Assets			
Operating lease assets	Operating lease right-of-use assets	$ 33,363	$ 36,543
Finance lease assets	Other assets	—	58
Total lease assets		$ 33,363	$ 36,601
Liabilities			
Current:			
Operating lease liabilities	Operating lease liabilities	$ 7,466	$ 5,244
Finance lease liabilities	Accrued expenses and other liabilities	—	64
Noncurrent:			
Operating lease liabilities	Operating lease liabilities, less current portion	34,823	39,942
Total lease liabilities		$ 42,289	$ 45,250

Information regarding our lease terms is as follows:

	Year Ended December 31,	
	2024	2023
Weighted-average remaining lease term:		
Operating leases	4.8 years	6.2 years
Finance leases	—	0.8 years
Weighted-average discount rate:		
Operating leases	9.9%	10.9%
Finance leases	—%	11.7%

The components of lease expense consist of the following (in thousands):

	Year Ended December 31,		
	2024	2023	2022
Operating lease costs	$ 10,277	$ 11,123	$ 11,093
Short-term lease costs	4,277	4,088	3,060
Finance lease costs (including right-of-use asset amortization and interest expense)	59	88	80
Variable lease costs	3,947	3,521	3,880
Total lease expense	$ 18,560	$ 18,820	$ 18,113

Cash paid for amounts included in the measurement of lease liabilities is as follows (in thousands):

	Year Ended December 31,		
	2024	2023	2022
Cash paid for operating leases (excluding variable lease costs)	$ 10,642	$ 9,538	$ 10,241
Financing cash flow from finance leases	64	77	58
Operating cash flow from finance leases	2	11	15

Future minimum lease payments as of December 31, 2024, including $11.5 million related to options to extend lease terms that are reasonably certain of being exercised, are presented in the following table (in thousands). Common area maintenance costs and taxes are not included in these payments.

Years Ending December 31:	Operating Leases
2025	$ 11,588
2026	9,728
2027	8,983
2028	9,248
2029	8,598
Thereafter	7,459
Total future minimum lease payments	55,604
Less: Interest	13,186
Less: Tenant improvement allowance receivable	129
Present value of operating lease liabilities	$ 42,289

There have been no material changes related to our existing lease agreements during the year ended December 31, 2024.

11. Revenue Interest Purchase Agreement

Revenue Interest Liability

On December 29, 2023, we entered into the RIPA with Infinity and Oberland. Pursuant to the RIPA, Oberland acquired certain initial Revenue Interests from us for a gross purchase price of $200.0 million paid on closing, less $7.5 million of issuance costs. Oberland had the option to purchase additional Revenue Interests from us in exchange for a $100.0 million Second Payment upon satisfaction of certain conditions in the RIPA, including receipt of approval from the FDA of our BLA for ANKTIVA on or before June 30, 2024.

On April 22, 2024, the FDA approved our product ANKTIVA and as a result, on May 13, 2024 Oberland purchased additional Revenue Interests from us for a gross purchase price of $100.0 million, less $3.1 million of issuance costs. The issuance costs incurred are being amortized to interest expense over the estimated term of the debt.

As consideration for the aforementioned payments, Oberland has the right to receive quarterly Revenue Interest Payments from us based on, among other things, a certain percentage of our net sales during such quarter, which are tiered payments ranging from 4.5% to 10.0% (before funding of the Second Payment, 3.0% to 7.0%) of the company's worldwide net sales, excluding those in China.

If the aggregate Revenue Interest Payments made to Oberland as of December 31, 2029 (Test Date) equal or exceed the Cumulative Purchaser Payments ($300.0 million) as of that date, the initially tiered revenue interest rate will be decreased to a single rate of 2.25% (before the funding of the Second Payment, 1.50%) of the company's worldwide net sales, excluding those in China. If the aggregate Revenue Interest Payments made to Oberland as of the Test Date are less than the aggregate amount of Cumulative Purchaser Payments as of the Test Date, then following the Test Date the initially tiered revenue interest rate will increase to a rate that, had such increased rate applied during the period from December 29, 2023 through December 31, 2029, it would have resulted in Oberland receiving aggregate Revenue Interest Payments (excluding certain payments detailed in the RIPA) equal to the Cumulative Purchaser Payments as of the Test Date. In addition, if aggregate Revenue Interest Payments made to Oberland as of the Test Date are less than the aggregate amount of Cumulative Purchaser Payments as of the Test Date, then the company must make the True-Up Payment.

Oberland's rights to receive Revenue Interest Payments under the RIPA shall terminate when Oberland has received payments (including any True-Up Payment) equal to 195.0% of the then Cumulative Purchaser Payments unless the RIPA is terminated prior to such date (subject to certain Call/Put Option scenarios as described below). If Oberland has not received total payments (including any True-Up Payment) equal to 195.0% of the then Cumulative Purchaser Payments on or before the twelfth anniversary of the RIPA, then the company shall be obligated to pay to Oberland an amount equal to 195.0% of the then Cumulative Purchaser Payments less the aggregate payments (including any True-Up Payments) made as of such date.

The company's obligations under the RIPA are guaranteed by certain of its subsidiaries meeting materiality thresholds set forth in the RIPA. To secure the company's obligations under the RIPA and the subsidiary guarantors' obligations under the guarantees, each of the company and the subsidiary guarantors has granted a security interest in substantially all its assets, subject to certain exceptions and limitations.

The RIPA contains affirmative and negative covenants and events of default, including covenants and restrictions that, among other things, restrict our ability to incur additional liens, incur additional indebtedness, make loans and investments, enter into transactions with affiliates, engage in mergers and acquisitions, engage in asset sales and exclusive licensing arrangements, and declare dividends to our stockholders, in each case, subject to certain exceptions set forth in the RIPA. As of December 31, 2024, the company was in compliance with all covenants.

The RIPA is considered a sale of future revenues and is accounted for as long-term debt recorded at amortized cost using the effective interest rate method. The company imputes interest expense associated with this liability using the effective interest rate method. The effective interest rate is calculated based on the rate that would enable the debt to be repaid in full over the anticipated life of the arrangement. The interest rate on this liability may vary during the term of the agreement depending on a number of factors, including the level of forecasted net sales. The company evaluates the interest rate quarterly based on its current net sales forecasts utilizing the prospective method. A significant increase or decrease in actual or forecasted net sales may materially impact the revenue interest liability, interest expense, other income, and the time period for repayment.

On December 10, 2024, the company entered into an amendment to the RIPA to add additional conditions to the payment of certain existing indebtedness. Such amendment did not have an impact on the valuation of the revenue interest liability or the embedded derivative liabilities related to the RIPA.

During the years ended December 31, 2024 and 2023, we recorded $39.7 million and $0.3 million of interest expense, respectively, related to this arrangement.

The following table summarizes the revenue interest liability activity during the years ended December 31, 2024 and 2023 (in thousands):

Revenue interest liability at inception	$	—
Proceeds from First Payment, net of issuance costs		192,509
Embedded contingent derivative liability related to First Payment		(34,500)
Issuance of common stock		(2,039)
Fair value of stock purchase option		(819)
Interest expense recognized		264
Revenue interest liability, at December 31, 2023		155,415
Proceeds from Second Payment, net of issuance costs		96,956
Embedded contingent derivative liability related to Second Payment		(6,150)
Revenue interest payment		(1,474)
Interest expense recognized		39,657
Revenue interest liability, at December 31, 2024	$	284,404

Embedded Derivative Liabilities

Under the RIPA, the company has a Call Option to terminate the RIPA and repurchase the Revenue Interests at any time upon advance written notice, subject to certain limitations set forth in the RIPA. Additionally, Oberland has a Put Option enabling them to terminate the RIPA and to require the company to repurchase the Revenue Interests upon enumerated events, such as a bankruptcy event, failure to make a payment, an uncured material breach, default in certain third-party agreements, a breach or default under any subordination agreements with respect to indebtedness to existing stockholders, or subordinated notes during certain time periods, judgments in excess of certain amounts against the company, a material adverse effect, the loss of regulatory approval of our product candidates or a change of control.

The required purchase price with respect to the Call Option and/or Put Option, as applicable, shall be (a) 120.0% of the Cumulative Purchaser Payments as of such date, if Oberland exercises the Put Option (other than in connection with a change of control) on or prior to the first anniversary the Closing Date, (b) 135.0% of the Cumulative Purchaser Payments as of such date, if the Put Option or the Call Option is exercised in connection with a change of control on or prior to the date that is eighteen (18) months after the Closing Date, and (c) in all other cases, (i) 175.0% of the Cumulative Purchaser Payments as of such date, if the Put Option or the Call Option is exercised no later than the date that is thirty six (36) months after the Closing Date, and (ii) 195.0% of the Cumulative Purchaser Payments as of such date, if the Put Option or the Call Option is exercised later than the date that is thirty six (36) months after the Closing Date, minus, in each case, the total payments made to Oberland on or prior to such date.

The aforementioned Call and Put Options are considered embedded derivatives requiring bifurcation as a single compound derivative instrument. The company estimated the fair value of the derivative liability using a “with-and-without” method. The “with-and-without” methodology involves valuing the whole instrument on an as-is basis and then valuing the instrument without the individual embedded derivative. The difference between the entire instrument with the embedded derivative compared to the instrument without the embedded derivative is the fair value of the derivative liability.

The company recorded $34.5 million for the initial fair value of the derivative liability upon the closing of the initial $200.0 million Revenue Interests acquired by Oberland. The company recorded an incremental $6.2 million for the fair value of the derivative liability upon the closing of the additional $100.0 million Revenue Interests acquired by Oberland in May 2024. The initial and incremental fair value allocated to the derivative liability is recorded against the RIPA as a debt discount, which is being amortized in *interest expense,* on the consolidated statement of operations over the expected term of the debt using the effective interest method. The embedded derivative is subsequently remeasured at fair value each reporting period, with the change in fair value being recorded in *change in fair value of derivative liabilities*, on the consolidated statement of operations.

The estimated probability and timing of underlying events triggering the exercisability of the Put Option contained in the RIPA, forecasted cash flows and the discount rate are significant unobservable inputs used to determine the estimated fair value of the entire instrument with the embedded derivative. As of December 31, 2024 and 2023, the discount rate used for valuation of the derivative liability was 10.4% and 12.1%, respectively.

The change in fair value of the derivative liabilities is as follows (in thousands):

Fair value, at December 31, 2023	$	34,500
Change in fair value		(14,850)
Embedded contingent derivative liability related to Second Payment		6,150
Fair value, at December 31, 2024	$	25,800

Stock Purchase and Option Agreement

In connection with the RIPA, we entered into an SPOA with Oberland pursuant to which we sold an aggregate of approximately $10.0 million of our common stock at $4.1103 per share in a private placement. Oberland also had an option to purchase up to an additional $10.0 million of our common stock, at a price per share to be determined by reference to the 30-day trailing volume weighted-average price of our common stock calculated from the date of exercise.

This stock purchase option was classified as a liability estimated at fair value at issuance. The initial $200.0 million received pursuant to the RIPA and $10.0 million received pursuant to the SPOA were allocated among the resulting financial instruments on a relative fair value basis, with $197.1 million allocated to the debt under the RIPA, $12.0 million allocated to the common stock issued under the SPOA, and $0.8 million allocated to the stock purchase option as of December 31, 2023.

In April 2024, Oberland exercised part of their option and purchased 858,990 shares of our common stock at an exercise price of $5.8208 per share generating net proceeds of approximately $4.9 million. In relation to this transaction, we recorded $7.6 million in *additional paid-in capital,* on the statement of stockholders' deficit during the year ended December 31, 2024. Following such exercise, approximately $5.0 million remains available for future exercise under the SPOA as of December 31, 2024.

This stock purchase option is classified in *accrued expenses and other liabilities*, on the consolidated balance sheet at its fair value and is subsequently remeasured at fair value each reporting period, with the change in fair value being recorded in *change in fair value of derivative liabilities*, on the consolidated statement of operations. The estimated fair value of the stock option purchase liability was computed using the calculated exercise price and discounted back to a present value at the risk-free rate with the following unobservable assumptions at the following dates:

	As of December 31,	
	2024	**2023**
Expected volatility	127.0 %	135.0 %
Risk-free rate	4.3 %	5.1 %

The change in fair value of the stock option purchase liability is as follows (in thousands):

Fair value, at December 31, 2023	$	819
Change in fair value		2,206
Exercise of stock option		(2,705)
Fair value, at December 31, 2024	$	320

12. Related-Party Debt

Our related-party debt is summarized below (in thousands):

	Balance as of December 31, 2024				
				Fair Value	
	Maturity Year	Interest Rate	Principal Amount	Amount	Leveling
Related-Party Convertible Note at Fair Value:					
$505 million December 2024 Promissory Note (4)	2027	Term SOFR +8.0%	$ 505,000	$ 461,877	Level 3

	Balances as of December 31, 2023				
	Maturity Year	Interest Rate	Principal Amount	Less: Unamortized Discounts	Total
Related-Party Nonconvertible Note:					
$505 million December 2023 Promissory Note - Tranche 1 (1), (2), (3)	2025	Term SOFR +8.0%	$ 125,000	$ 20,414	$ 104,586
Related-Party Convertible Notes:					
$300 million December 2021 Promissory Note (1), (2), (3)			$ 300,000	$ 26,091	$ 273,909
$50 million December 2022 Promissory Note (1), (2), (3)			50,000	4,349	45,651
$30 million June 2023 Promissory Note (2), (3)			30,000	2,609	27,391
$505 million December 2023 Promissory Note Tranche 2 (1)	2025	Term SOFR +7.5%	380,000	33,049	346,951
$30 million March 2023 Promissory Note (2), (4)	2025	Term SOFR +8.0%	30,000	—	30,000
$200 million September 2023 Promissory Note (2), (4)	2026	Term SOFR +8.0%	200,000	—	200,000
Total related-party convertible notes			$ 610,000	$ 33,049	$ 576,951

$505 million December 2024 Promissory Note

On December 10, 2024 in connection with an equity offering, the company and Nant Capital entered into a second amended and restated promissory note. Pursuant to the terms of the second amended and restated promissory note, Tranche 1 of the December 2023 Promissory Note with a principal amount of $125.0 million and Tranche 2 of the December 2023 Promissory Note with a principal amount of $380.0 million were combined into one convertible promissory note with a principal amount of $505.0 million with a maturity date of December 31, 2027. The $505.0 million December 2024 Promissory Note bears an interest rate of Term SOFR plus 8.0% per annum, payable on a quarterly basis. Pursuant to the terms of the second amended and restated promissory note, the noteholder, in its sole discretion, may convert all of the outstanding principal amount into shares of common stock at a conversion price of $5.4270 per share. In addition, the noteholder can request up to $50.0 million of the outstanding principal amount and accrued interest to be repaid upon consummation of a specified transaction.

In connection with the RIPA transaction, the outstanding related party convertible note was subordinated to the RIPA payment obligations.

The following table summarizes the estimated future contractual obligations of our related-party debt as of December 31, 2024 (in thousands):

	Principal Payments	Interest Payments (1)	Total
2025	$ —	$ 62,168	$ 62,168
2026	—	62,168	62,168
2027	505,000	62,168	567,168
Total	$ 505,000	$ 186,504	$ 691,504

(1) Interest payments on our promissory note are calculated based on Term SOFR plus the contractual spread per the loan agreement. The weighted-average interest rate on our promissory note as of December 31, 2024 was 12.34%.

Mandatory Prepayment Feature

The embedded derivative related to a contingently exercisable prepayment feature, which allows the noteholder to request up to a $50.0 million prepayment and accrued interest upon occurrence of a specified transaction (defined in the promissory note) was recorded as a derivative liability on the consolidated balance sheet and measured at fair value prior to the second amended and restated promissory note. The fair value of the derivative liability was determined at each period end using the with-and-without method, which assessed the likelihood and timing of a specified transaction that if triggered could have resulted in a repayment. Changes in the fair value of the derivative liability were reported in *change in fair value of derivative liabilities*, on the consolidated statement of operations.

Since the company elected the fair value option to account for the $505.0 million December 2024 Promissory Note, the embedded derivative is no longer required to be recorded separately but is considered when estimating the fair value of the $505.0 million December 2024 Promissory Note. The change in fair value of the contingently exercisable prepayment feature embedded derivative through December 10, 2024, the date of the $505.0 million December 2024 Promissory Note amendment, was $0.8 million and $0.8 million during the year ended December 31, 2023.

$300.0 million December 2021 Promissory Note

On December 17, 2021, the company executed a $300.0 million promissory note with Nant Capital, an affiliated entity under common control of our Founder, Executive Chairman and Global Chief Scientific and Medical Officer. The note bore an interest rate of Term SOFR plus 5.4% per annum, payable on a quarterly basis. The outstanding principal amount and any accrued and unpaid interest on advances were due on December 17, 2022. In the event of a default on the loan (as defined in both the original and amended and restated promissory notes), including if the company does not repay the loan at maturity, the company had the right, at its sole option, to convert the outstanding principal amount and accrued and unpaid interest due under this note into shares of the company's common stock at a price of $5.67 per share.

On August 31, 2022, the company and Nant Capital entered into an amended and restated promissory note, pursuant to which the maturity date of the promissory note was extended to December 31, 2023 and the interest rate was amended to Term SOFR plus 8.0% per annum.

On September 11, 2023, the company and Nant Capital entered into a letter amendment pursuant to which the maturity date of the promissory note was further extended to December 31, 2024.

On December 29, 2023 in connection with the RIPA, the company and Nant Capital entered into an amended and restated promissory note pursuant to which this existing promissory note was amended to be included in the Tranche 2 principal amount of the amended $505.0 million December 2023 promissory note, with a maturity date of December 31, 2025, and an interest rate of Term SOFR plus 7.5% per annum. Based on the terms of the amended and restated promissory note, the noteholder, at its sole discretion, could convert all of the Tranche 2 $380.0 million principal amount into shares of common stock at a conversion price of $8.2690 per share.

$125.0 million August 2022 Promissory Note

On August 31, 2022, the company executed a $125.0 million promissory note with Nant Capital. The note bears an interest rate of Term SOFR plus 8.0% per annum, payable on a quarterly basis. The company may prepay the outstanding promissory note, at any time, in whole or in part, without penalty.

On September 11, 2023, the company and Nant Capital entered into a letter amendment pursuant to which the maturity date of the promissory note was extended to December 31, 2024.

On December 29, 2023 in connection with the RIPA, the company and Nant Capital entered into an amended and restated promissory note letter agreement pursuant to which the existing promissory note was amended to be included in the Tranche 1 principal amount of the amended $505.0 million December 2023 promissory note, with a maturity date of December 31, 2025 and an interest rate of Term SOFR plus 8.0% per annum.

$50.0 million December 2022 Promissory Note

On December 12, 2022, the company executed a $50.0 million promissory note with Nant Capital. The note bore an interest rate of Term SOFR plus 8.0% per annum, payable on a quarterly basis. The company could prepay the outstanding promissory note, at any time, in whole or in part, without penalty. In the event of a specified transaction (as defined in the note), the noteholder could request the outstanding principal and interest due on the loan to be repaid in full upon consummation of such specified transaction.

On September 11, 2023, the company and Nant Capital entered into a letter amendment pursuant to which the maturity date of the promissory note was further extended to December 31, 2024.

On December 29, 2023 in connection with the RIPA, the company and Nant Capital entered into an amended and restated promissory note pursuant to which the existing promissory note was amended to be included in the Tranche 2 principal amount of the amended $505.0 million December 2023 promissory note, with a maturity date of December 31, 2025, and an interest rate of Term SOFR plus 7.5% per annum. Pursuant to the terms of the amended and restated promissory note, the investor, in its sole discretion, could convert all of the outstanding Tranche 2 principal amount into shares of common stock at a conversion price of $8.2690 per share. The noteholder could request up to $50.0 million of the Tranche 2 principal amount and accrued interest to be repaid upon consummation of such specified transaction.

$30.0 million March 2023 Promissory Note

On March 31, 2023, the company executed a $30.0 million promissory note with Nant Capital. This note bore interest at Term SOFR plus 8.0% per annum, payable on a quarterly basis. The outstanding principal amount and any accrued and unpaid interest was originally due on December 31, 2023. The company may prepay the outstanding promissory note, at any time, in whole or in part, without penalty. Upon receipt of a written notice of prepayment from the company, the noteholder could choose to convert the outstanding principal amount to be prepaid and the accrued and unpaid interest thereon into shares of the company's common stock at a price of $2.28 per share. Additionally, the noteholder could at its option convert the entire outstanding principal amount of the promissory note and accrued interest into shares of the company's common stock at a conversion price of $2.28 per share, at the option of the noteholder.

The company received net proceeds of approximately $29.9 million from this financing, net of a $0.1 million origination fee paid to the noteholder.

On September 11, 2023, the company and Nant Capital entered into a letter agreement pursuant to which the maturity date of the $30.0 million promissory note described above was extended from December 31, 2023 to December 31, 2024.

On December 29, 2023 in connection with the RIPA, the company and Nant Capital entered into a letter agreement pursuant to which the maturity date of this promissory note was extended to December 31, 2025.

On December 10, 2024 in connection with an equity offering, the company received a written notice from Nant Capital, the holder of the $30.0 million promissory note due December 31, 2025, of its election to convert the entire outstanding principal and accrued interest under the existing note into shares of the company's common stock. As of such date, the total outstanding principal amount and accrued and unpaid interest due under the existing note were converted into shares of the company's common stock. See Note 15 *"Stockholders' Deficit"* for more information.

$30.0 million June 2023 Promissory Note

On June 13, 2023, the company executed a $30.0 million promissory note with Nant Capital, pursuant to which, the company could request up to three (3) advances of $10.0 million each. The principal amount of each advance bore interest rate at Term SOFR plus 8.0% per annum, payable on a quarterly basis. The outstanding principal amount and any accrued and unpaid interest on advances was originally due on December 31, 2023. We could prepay the outstanding principal amount, together with any accrued interest, on any then-outstanding advances, at any time, in whole or in part, without premium or penalty, and without the prior consent of the noteholder upon five (5) days written notice to the noteholder.

We received net proceeds of approximately $29.9 million from this promissory note, net of a $0.1 million origination fee paid to Nant Capital.

On September 11, 2023, the company and Nant Capital entered into a letter amendment pursuant to which the maturity date of the promissory note was further extended to December 31, 2024.

On December 29, 2023 in connection with the RIPA, the company and Nant Capital entered into an amended and restated promissory note pursuant to which the existing promissory note was amended to be included in the Tranche 2 principal amount of the amended $505.0 million December 2023 promissory note, with a maturity date of December 31, 2025, and an interest rate of Term SOFR plus 7.5% per annum. Pursuant to the terms of the amended and restated promissory note the investor, in its sole discretion, could convert all of the Tranche 2 $380.0 million principal amount into shares of common stock at a conversion price of $8.2690 per share.

$200.0 million September 2023 Promissory Note

On September 11, 2023, the company executed a $200.0 million convertible promissory note with Nant Capital. The note bore interest at Term SOFR plus 8.0% per annum, payable on a monthly basis. The outstanding principal amount and any accrued and unpaid interest were due on September 11, 2026. We could prepay the outstanding principal amount, together with any accrued interest, at any time, in whole or in part, without premium or penalty upon five (5) days' written notice to the noteholder. The noteholder had the sole option to convert all (but not less than all) of the outstanding principal amount and accrued but unpaid interest into shares of the company's common stock at a conversion price of $1.9350 per share. The company received net proceeds of approximately $199.0 million from this financing, net of a $1.0 million origination fee paid to the noteholder.

On December 10, 2024 in connection with an equity offering, the company received a written notice from Nant Capital, the holder of the $200.0 million promissory note due September 11, 2026 of its election to convert the entire outstanding principal and accrued interest due under the existing note into shares of the company's common stock. As of such date, the total outstanding principal amount and accrued and unpaid interest due under the note were converted into shares of the company's common stock. See Note 15 *"Stockholders' Deficit"* for more information.

Footnotes to Related-Party Debt Tables

Debt Modification and Debt Extinguishments

(1) August 2022 Debt Extinguishment

On August 31, 2022, the company amended and restated the above fixed-rate notes payables held by Nant Capital, NantWorks, NantMobile and NCSC, which are entities affiliated with Dr. Soon-Shiong. Prior to the amendments and restatements, these notes bore and thereafter continued to bear interest at a per annum rate ranging from 3.0% to 6.0%, provided that the outstanding principal was and thereafter continued to be due and payable on September 30, 2025, and accrued and unpaid interest was or continued to be payable either upon maturity or, with respect to one of the notes, on a quarterly basis. Prior to the amendments and restatements, the company could and thereafter continued to be able to prepay the outstanding principal (together with accrued and unpaid interest), either in whole or in part, at any time without premium or penalty and without the prior consent of the noteholder, subject to an advance notice period of at least five business days during which the noteholder could convert the amount requested to be prepaid by the company into shares of the company's common stock, as part of the amendment and restatement.

The terms of these fixed-rate promissory notes were amended and restated to include a conversion feature that gave each noteholder, at its sole option, at any time (other than when the noteholder is in receipt of a written notice of prepayment from the borrower), the right to convert the entire outstanding principal amount and accrued and unpaid interest due under each note at the time of conversion into shares of the company's common stock at a price of $5.67 per share.

Since all of the above promissory notes were entered into or amended at the same time and with entities under common control, the company determined that the promissory notes were required to be evaluated collectively to accurately capture the economics of the transactions entered in contemplation of each other and contemporaneously. ASC 470-50 provides that a modification or an exchange that adds or eliminates a substantive conversion option as of the conversion date would always be considered substantial and require extinguishment accounting. Accordingly, as a result of the addition of the conversion feature to the fixed-rate promissory notes, the fixed-rate promissory notes and the variable-rate promissory notes were determined to be extinguished given the contemporaneous nature of the amendments. The company performed a valuation of the fixed-rate promissory notes and variable-rate promissory notes before and after amendments. Under this model, the company calculated a gain on extinguishment of $82.9 million, representing the difference between the fair value of the new and amended promissory notes and the carrying value of the extinguished debt, net of any unamortized related-party notes discounts plus the cash proceeds from the new promissory note. Since the debt was obtained from entities under common control, such gain was recorded in *additional paid-in capital*, on the consolidated statement of stockholders' deficit during the year ended December 31, 2022. Also, the difference between the face values of the new and amended promissory notes (and accrued interest on the date of the amendment) and the fair values of the new and restated promissory notes was recorded as a debt discount to be amortized to interest expense over the remaining term (or until conversion in the case of fixed-rate promissory notes) of the respective promissory notes. During the years ended December 31, 2023 and 2022, we recorded amortization of related-party notes discounts totaling $42.4 million and $16.3 million, respectively, in *interest expense*, on the consolidated statement of operations.

The fair values of the promissory notes without a holder conversion option were estimated using discounted cash flow analyses, based on market rates available to the company for similar debt at issuance after consideration of default and credit risk and the level of subordination. The fair values of the fixed-rate promissory notes, which were each modified to include a holder conversion option, were determined based on a binomial lattice convertible note model. The analysis involved the construction of various intermediate lattices: stock price tree, conversion value tree, conversion probability tree, and discount rate tree. Since certain of the factors analyzed are considered to be unobservable inputs, both the discounted cash flow model and the lattice model are considered to be Level 3 valuations. Significant unobservable inputs used for the discounted cash flow analysis included market yields from 18.0% to 24.8% and a risk-free rate of 4.1%, and the significant unobservable inputs used for the binomial lattice model included a volatility of 84.9%, a market yield of 17.4% and a risk-free rate of 3.5%.

On December 12, 2022, the company received written notice from NantWorks, the holder of an existing convertible promissory note of NantCell, a wholly-owned subsidiary of the company, of its election to convert the NantCell promissory note into shares of the company's common stock. As of such date, the holder of the NantCell note converted the entire $56.6 million of outstanding principal and accrued and unpaid interest due under the note into 9,986,920 shares of the company's common stock at a price of $5.67 per share in accordance with the terms of the promissory note.

(2) September 11, 2023 Debt Modification

On September 11, 2023, the company entered into a stock purchase agreement with Nant Capital, NantMobile and NCSC pursuant to which the holders exchanged promissory notes totaling approximately $270.0 million in aggregate principal amount and accrued unpaid interest for an aggregate of 209,291,936 shares of common stock at an exchange price of $1.29 per share. As a result of the exchange, the company was forever released and discharged from all its obligations and liabilities under the notes.

On September 11, 2023, the company and Nant Capital entered into a series of letter agreements pursuant to which the maturity date of the related-party nonconvertible notes described above totaling $505.0 million in principal and the $30.0 million March 2023 Promissory Note was extended from December 31, 2023 to December 31, 2024. In addition, the company entered into the $200.0 million September 2023 promissory note with Nant Capital. No other material terms or conditions of these promissory notes were modified.

Since all of the above promissory notes were entered into or amended at the same time on September 11, 2023 and with entities under common control, the company determined that the promissory notes were required to be evaluated collectively to accurately capture the economics of the transactions entered in contemplation of each other and contemporaneously. Pursuant to ASC 470-50, as the terms of the amendment were not substantially different than the terms of the promissory notes prior to the amendment, the amendment was accounted for as a debt modification. The unamortized debt discounts from the promissory notes are being amortized as an adjustment to interest expense over the remaining term of modified promissory notes that are not recorded at fair value using the effective interest rate method. Also, a $29.6 million increase in fair value of the embedded conversion feature from the debt modification was accounted for as a debt discount to the $200.0 million convertible note that is not recorded at fair value, and a $1.6 million increase in fair value of the embedded conversion feature related to the promissory note recorded at fair value was accounted for as interest expense during the year ended December 31, 2023. Such increase in fair values of the embedded conversion features totaling $31.2 million has been recorded with a corresponding increase in *additional paid-in capital*, on the consolidated statement of stockholders' deficit.

(3) December 29, 2023 Debt Extinguishment

On December 29, 2023 in connection with the RIPA, the company and Nant Capital entered into an amended and restated promissory note and a letter amendment for the following outstanding promissory notes. Pursuant to the terms of the amended and restated promissory note, the amended $505.0 million December 2023 promissory note became comprised of a Tranche 1 with principal amount of $125.0 million which was previously the $125.0 million August 2022 promissory note before amendment, and a Tranche 2 with principal amount of $380.0 million, which was made up of the previous $300.0 million December 2021 promissory note, $50.0 million December 2022 promissory note and $30.0 million June 2023 promissory note. In addition, the amendment allowed Nant Capital, in its sole discretion, to convert all the Tranche 2 principal amount of $380.0 million of the amended promissory note into shares of common stock. The conversion price was subsequently determined at $8.2690 per share based on the agreement. The maturity date of the amended promissory note was December 31, 2025. Pursuant to the terms of the letter amendment, the maturity date of the $30.0 million March 2023 promissory note was extended from December 31, 2024 to December 31, 2025. Also, in connection with the RIPA transaction, all outstanding related-party promissory notes became subordinated to the RIPA payment obligations.

The following table summarizes the Nant Capital promissory notes before the amendments on December 29, 2023 (principal amount in thousands):

	Principal Amount	Maturity Year	Conversion Price	Interest Rate
Related-Party Nonconvertible Note:				
$125 million August 2022 Promissory Note	$ 125,000	2024		Term SOFR +8.0%
Related-Party Convertible Notes:				
$300 million December 2021 Promissory Note	$ 300,000	2024		Term SOFR +8.0%
$50 million December 2022 Promissory Note	50,000	2024		Term SOFR +8.0%
$30 million June 2023 Promissory Note	30,000	2024		Term SOFR +8.0%
$30 million March 2023 Promissory Note	30,000	2024	$2.2800	Term SOFR +8.0%
$200 million September 2023 Promissory Note	200,000	2026	$1.9350	
Total related-party promissory notes before amendments	$ 735,000			

The following table summarizes the Nant Capital promissory notes after the amendments on December 29, 2023 (principal amount in thousands):

	Principal Amount	Maturity Year	Conversion Price	Interest Rate
Related-Party Nonconvertible Note:				
$505 million December 2023 Promissory Note – Tranche 1	$ 125,000	2025		Term SOFR +8.0%
Related-Party Convertible Notes:				
$300 million December 2021 Promissory Note	$ 300,000			
$50 million December 2022 Promissory Note	50,000			
$30 million June 2023 Promissory Note	30,000			
$505 million December 2023 Promissory Note – Tranche 2	380,000	2025	$8.2690	Term SOFR +7.5%
Total $505 million December 2023 Promissory Note	505,000			
$30 million March 2023 Promissory Note	30,000	2025	$2.2800	Term SOFR +8.0%
$200 million September 2023 Promissory Note	200,000	2026	$1.9350	Term SOFR +8.0%
Total related-party promissory notes after amendments	$ 735,000			

Since all of the above outstanding promissory notes were amended at the same time, with entities under common control, the company determined that the promissory notes were required to be evaluated collectively to accurately capture the economics of the transactions entered in contemplation of each other and contemporaneously. Also, in accordance with ASC 470-50 the company used the debt terms that existed before the September 11, 2023 modification to determine whether the modification was substantially different, as the September 11, 2023 modification was within a year of the transaction, and the promissory notes, at that time, had been modified without being deemed to be substantially different. As the modifications (September 11, 2023 and December 29, 2023 on a cumulative basis) added a substantive conversion feature to the promissory notes, these promissory notes were determined to be extinguished given the contemporaneous nature of the amendments. The company performed a valuation of all the promissory notes before and after amendments. Under this model, the company calculated a loss on extinguishment of $318.8 million, representing the difference between the fair value of the amended promissory notes and the carrying value of the extinguished debt, net of any unamortized related-party notes discounts. Since the debt was obtained from entities under common control, such loss was recorded in *additional paid-in capital.* In addition, a debt premium totaling $354.9 million, calculated as the difference between the fair values of certain promissory notes after modifications and their respective face values, was also recorded in *additional paid-in capital.* Collectively, a net gain on debt extinguishment of $36.1 million was recorded in *additional paid-in capital,* on the consolidated statement of stockholders' deficit for the year ended December 31, 2023. Also, the difference between face values of certain new and amended promissory notes and their respective fair values of $53.1 million was recorded as a debt discount to be amortized as interest expense over the remaining term. During the year ended December 31, 2023, we recorded amortization of related-party notes discounts totaling $0.5 million in *interest expense,* on the consolidated statement of operations related to the new and amended promissory notes.

In regard to the Tranche 2 principal amount of the $505.0 million December 2023 promissory note, the company identified an embedded derivative related to a contingent exercisable prepayment feature of the promissory note, which allowed the noteholder to request up to a $50.0 million prepayment of the promissory note and accrued interest upon the occurrence of a specified transaction. After the debt extinguishment, the company concluded that this promissory note was issued at a substantial discount, so the embedded derivative that was contingently exercisable was required to be bifurcated and accounted separately from the debt host instrument. The fair value of the embedded derivative was estimated at $0.8 million as of December 31, 2023, using a "with and without" method, which assesses the likelihood and timing of the specified transaction to be triggered and result in a repayment. The estimated fair value was computed with the following unobservable assumptions:

	As of Amendment Date December 29, 2023
Expected market yield	23.2 %
Expected volatility	118.0 %
Risk-free rate	4.8 %

The fair value of Tranche 1 principal amount of the amended $505.0 million December 2023 promissory note, which had no noteholder conversion option, was estimated using discounted cash flow analyses, based on market rates available to the company for similar debt at issuance after consideration of default and credit risk and the level of subordination. The fair value of Tranche 2 of the amended promissory note, which was modified to include a noteholder conversion option, was determined based on a binomial lattice convertible note model. The analysis involved the construction of various intermediate lattices: stock price tree, conversion value tree, conversion probability tree, and discount rate tree. Since certain of the factors analyzed were considered to be unobservable inputs, both the discounted cash flow model and the lattice model are considered to be Level 3 valuations. The effective unamortized debt discount rate of the amended Tranche 1 and Tranche 2 principal amount of the $505.0 million December 2023 promissory note was 23.65% and 18.04%, respectively. The estimated fair value was computed with the following unobservable assumptions:

	As of Amendment Date December 29, 2023
Expected market yield	23.2 %
Expected volatility	118.0 %
Risk-free rate	4.4 %

The fair value of the $200.0 million September 2023 promissory note was determined using the binomial lattice model with the following unobservable assumptions:

	As of Amendment Date December 29, 2023
Expected market yield	23.3 %
Expected volatility	119.3 %
Risk-free rate	5.2 %

Prior to December 29, 2023, the $30.0 million March 2023 promissory note was accounted for under the ASC 825-10-15-4 FVO election. Under the FVO election, the note was initially measured at its issue-date estimated fair value and subsequently remeasured at estimated fair value on a recurring basis at each reporting period date. The estimated fair value of the convertible note was computed using the binomial lattice model with the following unobservable assumptions before it was modified on December 29, 2023. After the debt extinguishment, the note was accounted for under the amortized cost basis.

	As of Amendment Date December 29, 2023
Expected market yield	23.5 %
Expected volatility	138.0 %
Risk-free rate	5.2 %

The change in the carrying value of this note was as follows (in thousands):

Fair value at issuance date, March 31, 2023	$	29,850
Change in fair value		36,203
Gain on debt extinguishment with entities under common control		(36,053)
Carrying value, December 29, 2023	$	30,000

(4) December 10, 2024 Debt Extinguishment

On December 10, 2024 in connection with an equity offering, the company and Nant Capital entered into a second amended and restated promissory note. Pursuant to the terms of the second amended and restated promissory note, Tranche 1 of the December 2023 Promissory Note with a principal amount of $125.0 million and Tranche 2 of the December 2023 Promissory Note with a principal amount of $380.0 million were combined into one convertible promissory note with a principal amount of $505.0 million with a maturity date of December 31, 2027. The $505.0 million December 2024 Promissory Note bears an interest rate of Term SOFR plus 8.0% per annum, payable on a quarterly basis. Pursuant to the terms of the second amended and restated promissory note, the noteholder, in its sole discretion, may convert all of the outstanding principal amount into shares of common stock at a conversion price of $5.4270 per share. In addition, the noteholder can request up to $50.0 million of the outstanding principal amount and accrued interest to be repaid upon consummation of a specified transaction. Also, on the same date, the company received a written notice from Nant Capital, the holder of the $30.0 million March 2023 Promissory Note due on December 31, 2025 and the $200.0 million September 2023 Promissory Note due on September 11, 2026 of its election to convert the entire outstanding principal and accrued interests of the such promissory notes into shares of the company's common stock (the "Converted Promissory Notes"). As of such date, the total outstanding principal amount and accrued and unpaid interests due under the Converted Promissory Notes were converted into shares of the company's common stock.

Since the $505.0 million December 2024 Promissory Note, together with the Converted Promissory Notes, were executed contemporaneously and in contemplation with one another with entities under common control, the company evaluated these transactions collectively as a single unit of account to accurately capture the economics of the transactions. The company determined the fair value of the conversion feature before and after the above transactions to assess whether there is a substantial change in fair value. The company used binomial lattice models for the "with" scenario and discounted cash flow model for the "without" scenario. The company determined that the fair value of the conversion feature before modification is substantially different than the fair value after modification, and as such, these transactions were accounted for as debt extinguishment in accordance with ASC 470-50. Under this model, the company calculated a gain on debt extinguishment of $10.4 million, which represents the difference between the: (a) fair value of the December 2024 Promissory Note and the reacquisition price of the Converted Promissory Notes on the date of conversion; and (b) carrying value of the extinguished debt, net of any unamortized related party notes discounts plus, the debt premium previously recognized in *additional paid-in capital*, on the consolidated statement of stockholders' deficit as a result of the December 29, 2023 Debt Extinguishment. Since the debt was obtained from entities under common control, such gain on extinguishment was recorded in *additional paid-in capital*, on the consolidated statement of stockholders' deficit.

Due to the conversion of the Converted Promissory Notes, the Company also recorded $188.5 million in *additional paid-in capital*, on the consolidated statement of stockholders' deficit as of December 31, 2024. This represents the difference between the reacquisition price of the Converted Promissory Notes on the date of conversion and the debt premium previously recognized in *additional paid-in capital*, on the consolidated statement of stockholders' deficit as a result of the December 29, 2023 Debt Extinguishment. See Note 15 *"Stockholders' Deficit"* for more information.

The estimated fair value of the Converted Promissory Notes were computed with the following unobservable assumptions at the amendment date on December 10, 2024:

	$30 million March 2023 Promissory Note	$200 million September 2023 Promissory Note
Binomial lattice model:		
Expected market yield	18.5 %	18.6 %
Expected volatility	103.2 %	118.6 %
Risk-free rate	4.2 %	4.2 %
Discounted cash flow model:		
Discount rate	18.5 %	18.6 %

The company elected the fair value option for recognizing the $505.0 million December 2024 Promissory Note under ASC 825-10-15-4. Under the FVO election, the note was initially measured at estimated fair value upon issuance and is remeasured at estimated fair value on a recurring basis at each reporting period date. The estimated fair value of the convertible note was computed using the following unobservable assumptions at the following dates:

	Immediately Before the Amendment on December 10, 2024	Immediately After the Amendment on December 10, 2024	As of December 31, 2024
Binomial lattice model:			
Expected market yield	18.5 %	18.7 %	19.3 %
Expected volatility	103.6 %	115.1 %	125.6 %
Risk-free rate	4.2 %	4.1 %	4.3 %
Discounted cash flow model:			
Discount rate	18.5 %	18.7 %	19.3 %

The change in the carrying value of this note was as follows (in thousands):

Fair value at issuance date, December 10, 2024	$	518,378
Interest payment		(11,808)
Change in fair value, including $1.2 million related to instrument-specific credit risk		(44,693)
Ending fair value, at December 31, 2024	$	461,877

The following tables summarize the interest expense for our related-party promissory notes during the years ended December 31, 2024 and 2023 (in thousands):

	Year Ended December 31, 2024	
	Interest Expense	Debt Discount Amortization
$505 million December 2024 Promissory Note	$ 3,585	$ —
$505 million December 2023 Promissory Note Tranche 1	15,281	8,454
$505 million December 2023 Promissory Note Tranche 2	44,658	14,133
$30 million March 2023 Promissory Note	3,667	—
$200 million September 2023 Promissory Note	24,810	—
Total	$ 92,001	$ 22,587

	Year Ended December 31, 2023	
	Interest Expense	Debt Discount Amortization
$300 million December 2021 Promissory Note (1)	$ 39,653	$ 27,967
$125 million August 2022 Promissory Note (1)	16,521	5,962
$50 million December 2022 Promissory Note (1)	6,609	478
$30 million March 2023 Promissory Note (1)	4,590	—
$30 million June 2023 Promissory Note	2,096	258
$200 million September 2023 Promissory Note	8,185	2,586
Related-Party Fixed-Rate Promissory Notes	8,799	5,145
Total	$ 86,453	$ 42,396

(1) Balances include the amortization of debt discount totaling $0.5 million recorded during the period from December 29, 2023 to December 31, 2023. The interest expense recorded during this period was $0.4 million.

13. Related-Party Agreements

We conduct business with several affiliates under written agreements and informal arrangements. Below is a summary of outstanding balances and a description of significant relationships (in thousands):

	As of December 31,	
	2024	2023
Due from related party–NantBio	$ —	$ 1,294
Due from related party–NantWorks	161	541
Due from related party–Brink	59	62
Due from related parties–Various	73	122
Total due from related parties	$ 293	$ 2,019
Due to related party–NantBio	$ —	$ 943
Due to related party–Duley Road	134	136
Due to related party–the Clinic	21	57
Due to related parties–Various	18	—
Total due to related parties	$ 173	$ 1,136

Our Founder, Executive Chairman and Global Chief Scientific and Medical Officer also founded and has a controlling interest in NantWorks, which is a collection of companies in the healthcare and technology space. As described below, we have entered into arrangements with NantWorks, and certain affiliates of NantWorks, to facilitate the development of new immunotherapies for our product pipeline. Affiliates of NantWorks are also affiliates of the company due to the common control by and/or common ownership interest of our Founder, Executive Chairman, Global Chief Scientific and Medical Officer, and principal stockholder.

NantWorks, LLC

Shared Services Agreement

Under the amended and restated shared services agreement with NantWorks dated as of June 2016, but effective as of August 2015, NantWorks, a related party, provides corporate, general and administrative, certain research and development, and other support services to us, and we provide certain of such services to them. The receiving party is charged for the services at cost plus reasonable allocations of employee benefits, facilities and other direct or fairly allocated indirect costs that relate to the employees providing the services. During the years ended December 31, 2024, 2023 and 2022, we recorded $2.6 million, $3.3 million and $3.8 million, respectively, in *selling, general and administrative expense*, and $3.3 million, $2.2 million, and $0.9 million, respectively, of expense reimbursements under this arrangement in *research and development expense*, on the consolidated statements of operations. These amounts exclude certain general and administrative expenses provided by third-party vendors directly for our benefit, which were reimbursed to NantWorks based on those vendors' invoiced amounts without markup by NantWorks.

As of December 31, 2024 and 2023, we had a receivable of $0.2 million and $0.5 million, respectively, for all agreements with NantWorks, which are included in *due from related parties,* on the consolidated balance sheets. We also recorded $3.0 million and $1.0 million of prepaid expenses for various services that we expect will be passed through to the company from NantWorks as of December 31, 2024 and 2023, respectively, which are included in *prepaid expenses and other current assets*, on the consolidated balance sheets.

Facility License Agreement

In 2015, we entered into a facility license agreement with NantWorks for approximately 9,500 rentable square feet of office space in Culver City, California, which was converted to a research and development laboratory and a cGMP manufacturing facility. In 2020, we amended this agreement to extend the term of this license agreement through December 31, 2021. Commencing January 1, 2022, the license fee increased by 3% to approximately $56,120 per month.

On May 6, 2022, we amended our facility license agreement with NantWorks to expand the licensed premises by 36,830 rentable square feet to an aggregate total of 46,330 rentable square feet. Effective May 1, 2022, the license fee is approximately $273,700 per month, which is subject to a 3% increase commencing on January 1 of each year. The space continues to be rented on a month-to-month basis, which can be terminated by either party with at least 30 days' prior written notice to the other party. During the years ended December 31, 2024, 2023 and 2022, we recorded license fee expense for this facility totaling $3.5 million, $3.4 million, and $2.4 million, respectively, in *research and development expense*, on the consolidated statements of operations.

Immuno-Oncology Clinic, Inc.

We have entered into multiple agreements with the Clinic to conduct clinical trials related to certain of our product candidates. The Clinic is a related party as it is owned by an officer of the company and NantWorks manages the administrative operations of the Clinic.

In 2021, we completed a review of alternative structures that could support our more complex clinical trial requirements and made a decision to explore a potential transition of clinical trials at the Clinic to a new structure (including contracting with a new, non-affiliated professional corporation) to be determined and agreed upon by all parties. We continue discussions with potential partners around such alternative structures.

Related to clinical trial and transition services provided by the Clinic, during the years ended December 31, 2024, 2023 and 2022, we recorded $2.6 million, $2.2 million, and $2.4 million, respectively, in *research and development expense*, on the consolidated statements of operations. As of December 31, 2024 and 2023, we owed the Clinic an immaterial amount and $0.1 million, respectively, which are included in *due to related parties*, on the consolidated balance sheets.

Brink Biologics, Inc.

In 2015, we entered into an agreement with Brink whereby we granted Brink worldwide exclusive licenses for the use of certain cell lines and intellectual property in non-clinical laboratory testing. Brink is a related party as our Founder, Executive Chairman and Global Chief Scientific and Medical Officer, and our Chief Corporate Affairs Officer and member of our Board of Directors, collectively own more than 50% of Brink's outstanding shares. During the years ended December 31, 2024, 2023, and 2022, we recognized revenue of an immaterial amount related to this license.

NantBio, Inc.

In August 2018, we entered into a supply agreement with NCSC, a 100% owned subsidiary of NantBio. Under this agreement, we agreed to supply VivaBioCell's proprietary GMP-in-a-Box bioreactors and related consumables, made according to specifications mutually agreed to with both companies. The agreement had an initial term of five years and renews automatically for successive one-year terms unless terminated by either party in the event of material default upon prior written notice of such default and the failure of the defaulting party to remedy the default within 30 days of the delivery of such notice, or upon 90 days' prior written notice by NCSC.

During the years ended December 31, 2024, 2023 and 2022, we recognized no revenue. As of December 31, 2024 and 2023, we recorded $0.1 million of deferred revenue for bioreactors that were delivered but not installed in *accrued expenses and other liabilities*, on the consolidated balance sheets. As of December 31, 2023, we recorded a payable of $0.9 million in *due to related parties,* on the consolidated balance sheet related to this agreement. The payable was settled as of June 30, 2024.

In 2018, we entered into a shared service agreement pursuant to which we are charged for services at cost, without mark-up or profit by NantBio, but including reasonable allocations of employee benefits related to the employees providing the services. In April 2019, we agreed with NantBio to transfer certain NantBio employees and associated research and development projects to the company. As of December 31, 2023, we recorded a receivable of $1.3 million in *due from related parties,* on the consolidated balance sheet for amounts we paid on behalf of NantBio during the year ended December 31, 2019. The receivable was settled as of June 30, 2024.

605 Doug St, LLC

In 2016, we entered into a lease agreement with 605 Doug St, LLC, an entity owned by our Founder, Executive Chairman and Global Chief Scientific and Medical Officer, for approximately 24,250 rentable square feet in El Segundo, California, which has been converted to a research and development laboratory and a cGMP manufacturing facility. The lease

term was from July 2016 through July 2023. In June 2023, we exercised the option to extend the lease for one additional three-year term through July 2026. The base rent is approximately $72,385 per month, with annual increases of 3% that began in July 2017. During the years ended December 31, 2024, 2023 and 2022, we recorded lease expense for this facility of $0.9 million in *research and development expense*, on the consolidated statements of operations.

Duley Road, LLC

In 2017, we entered into a lease agreement with Duley Road, a related party that is indirectly controlled by our Founder, Executive Chairman and Global Chief Scientific and Medical Officer, for approximately 11,980 rentable square feet of office and cGMP manufacturing facility space in El Segundo, California. The lease term was originally from February 2017 through October 2024. We had and continue to have the option to extend the initial term for two consecutive five-year periods through October 2034. The base rent is approximately $40,700 per month, with annual increases of 3%. Effective October 3, 2023, we exercised the first option to extend the lease for one additional five-year term through October 31, 2029.

Effective in January 2019, we entered into two lease agreements with Duley Road for a second building located in El Segundo, California. The first lease is for the first floor of the building with approximately 5,650 rentable square feet. The lease has a seven-year term that commenced in September 2019. The second lease is for the second floor of the building with approximately 6,488 rentable square feet. The lease has a seven-year term that commenced in July 2019. Both floors of the building are used for research and development and office space. We have options to extend the initial terms of both leases for two consecutive five-year periods through 2036. The base rent for the two leases is approximately $35,800 per month, with annual increases of 3%.

During the years ended December 31, 2024, 2023 and 2022, we recorded rent expense for these leases totaling $1.0 million, $0.9 million, and $0.8 million, respectively, in *research and development expense*, on the consolidated statements of operations. As of December 31, 2024 and 2023, we recorded $0.1 million of lease-related payables to Duley Road in *due to related parties*, on the consolidated balance sheets.

605 Nash, LLC

In February 2021, but effective on January 1, 2021, we entered into a lease agreement with 605 Nash, a related party, whereby we leased approximately 6,883 rentable square feet (the Initial Premises) in a two story mixed use building containing approximately 64,643 rentable square feet at 605-607 Nash Street in El Segundo, California. This facility is used primarily for pharmaceutical development and manufacturing purposes. The lease term commenced in January 2021 and was originally set to expire in December 2027 and included an option to extend the lease for one three-year term through December 2030. The base rent is approximately $20,300 per month with an annual increase of 3% on January 1 of each year during the initial term, and if applicable, during the option term. In addition, under the agreement, we are required to pay our share of estimated property taxes and operating expenses.

In May 2021, but effective on April 1, 2021, we entered into an amendment to our Initial Premises lease with 605 Nash. The amendment expanded the leased square feet by approximately 57,760 rentable square feet (the Expansion Premises). The lease term of the Expansion Premises commenced in April 2021 and expires in March 2028, whereby the company has one option to extend the initial term for three years. Per the terms of the amendment, the term of the Initial Premises lease was extended for an additional three months and now expires on March 31, 2028. Base rent for the Expansion Premises is approximately $170,400 per month with annual increases of 3% on April 1 of each year. We are responsible for the buildout of the facility space and associated costs.

During the years ended December 31, 2024, 2023, and 2022, we recorded rent expense for the Initial and Expansion Premises leases totaling $2.2 million in *research and development expense,* on the consolidated statements of operations. The terms of initial and amended leases provided for tenant improvement allowances totaling $2.9 million for costs and expenses related to improvements made by us to the Initial and Expansion Premises, which was received from the landlord in 2023.

557 Doug St, LLC

After transferring all outstanding membership interests in 557 Doug St, LLC to Nant Capital (a related party controlled by Dr. Soon-Shiong) in September 2021, we entered into a lease agreement with Nant Capital for the improved property located at 557 South Douglas Street, El Segundo, California with a building area of approximately 36,434 rentable square feet (the Douglas Property). Pursuant to the terms of the agreement, we leased back the Douglas Property for an initial lease term of

seven years, which commenced on September 27, 2021. The monthly base rent under the lease was approximately $81,976 per month with an annual increase of 3% on October 1 of each year beginning in 2022 during the initial term. For the first two years under the lease, we would not be charged rent; we would begin paying rent on October 1, 2023 at the current monthly base rent. We prepaid the first month rent and security deposit totaling $0.2 million upon execution of the lease.

Effective May 31, 2022, we executed a lease termination agreement with Nant Capital under which we received a full refund of the first month's rent and security deposit totaling $0.2 million that we paid upon execution of the lease. Prior to the termination of the lease, we recorded rent expense of $0.4 million during the year ended December 31, 2022 in *research and development expense*, on the consolidated statement of operations. During the year ended December 31, 2022, we recognized a gain of $0.6 million on the disposal of this lease in *other income (expense), net*, on the consolidated statement of operations.

420 Nash, LLC

On September 27, 2021, we entered into a lease agreement with 420 Nash, LLC, a related party, whereby we leased an approximately 19,125 rentable square foot property located at 420 Nash Street, El Segundo, California, to be used primarily for the warehousing and storage of drug manufacturing supplies, products and equipment, and ancillary office space.

Under the terms of the lease agreement, the lease term began on October 1, 2021 and expires on September 30, 2026. The base rent is approximately $38,250 per month with an annual increase of 3% on October 1 of each year beginning in 2022 during the initial term. The company is responsible for the payment of real property taxes, repairs and maintenance, improvements, insurance, and operating expenses during the term of the lease. We received a rent abatement for the first month of the lease, and a one-time improvement allowance of $15,000 from the landlord that was credited against base rent obligations for the second month of the lease.

The company has options to extend the lease term for two additional consecutive periods of five years each. At the beginning of each option term, the initial monthly base rent will be adjusted to market rent (as defined in the lease agreement) with an annual increase of 3% during the option term. We have included the first option to extend the lease term for five years as part of the initial term of the lease as it is reasonably certain that we will exercise the option, which implies lease expiration in September 2031. During the years ended December 31, 2024, 2023, and 2022 we recorded rent expense for this lease totaling $0.5 million in *research and development expense*, on the consolidated statements of operations.

23 Alaska, LLC

On May 6, 2022, we entered into a lease agreement with 23 Alaska, LLC, a related party, for a 47,265 rentable square foot facility located at 2335 Alaska Ave., El Segundo, California, to be used primarily for pharmaceutical development and manufacturing, research and development, and office space.

Under the terms of the agreement, the lease term began on May 1, 2022 and was to expire on April 30, 2027. The base rent was approximately $139,400 per month with an annual increase of 3% on May 1 of each year beginning in 2023 during the initial term. We were also required to pay $7,600 per month for parking during the initial term. The company was responsible for the payment of real property taxes, repairs and maintenance, improvements, insurance, and operating expenses during the term of the lease.

The company was responsible for the costs associated with the buildout of the premises and was to receive a one-time tenant improvement allowance of approximately $0.9 million from the landlord. As of December 31, 2022, we re-evaluated plans for the future development of the facility and deemed it unlikely to claim any of the allowance during the reimbursement time frame. As such, during the year ended December 31, 2022 we wrote off the entire allowance receivable of $0.9 million.

Effective August 31, 2023, we executed a lease termination agreement with the lessor under which we received a full refund of the security deposit totaling $0.1 million that we paid upon execution of the lease. During the years ended December 31, 2023 and 2022, we recorded $1.2 million of rent expense for this lease in *research and development expense*, on the consolidated statements of operations. During the year ended December 31, 2023, we recognized a gain of $0.6 million on the disposal of this lease in *research and development expense*, on the consolidated statement of operations.

14. Warrant Liabilities

December 2022 Warrants

In connection with the December 12, 2022 RDO, the company issued 9,090,909 warrants with an exercise price of $6.60 per share. The warrants became immediately exercisable on December 12, 2022 and expired in full on December 12, 2024.

We classified the warrants as a liability at their fair value determined using the Black-Scholes option pricing model. The fair value of the warrants was estimated at $35.1 million at the issuance date. Of the placement agent fees and other offering costs totaling $3.0 million, $1.1 million was allocated to the warrants and recorded in *other income (expense), net,* on the consolidated statement of operations on the date of the transaction.

February 2023 Warrants

In connection with the February 15, 2023 RDO, the company issued 14,072,615 warrants with an exercise price of $4.2636 per share. The warrants became immediately exercisable on February 17, 2023 and expire two years after the initial issuance date. On July 25, 2023, the company amended the terms of the warrant, reducing the exercise price of the warrants from $4.2636 per share to $3.2946 per share and extending the expiration date of the warrants until July 24, 2026.

We classified the warrants as a liability at their fair value determined using the Black-Scholes option pricing model. The fair value of warrants was estimated at $23.7 million at the issuance date. Of the placement agent fees and other offering costs totaling $3.0 million, $1.0 million was allocated to the warrants and recorded in *other income (expense), net,* on the consolidated statement of operations on the date of the transaction. Since the warrants were classified as liabilities and measured at fair value, we recognized the change of $7.3 million in fair value of warrant liability in earnings due to the warrant modification.

July 2023 Warrants

In connection with the July 20, 2023 RDO, the company issued 14,569,296 warrants with an exercise price of $3.2946 per share. These warrants became immediately exercisable on July 25, 2023 and expire on July 24, 2026.

We classified the warrants as a liability at their fair value determined using the Black-Scholes option pricing model. The fair value of warrants was estimated at $25.8 million at the issuance date. Of the placement agent fees and other offering costs totaling $2.5 million, $1.0 million was allocated to the warrants and recorded in *other income (expense), net,* on the consolidated statement of operations on the date of the transaction.

Warrant Liabilities

The following table summarizes the change in carrying amount of warrant liabilities measured at fair value during the years ended December 31, 2024, 2023, and 2022 (in thousands):

	Total	December 2022 Warrants	February 2023 Warrants	July 2023 Warrants
Fair value at issuance, December 12, 2022	$ 35,096	$ 35,096	$ —	$ —
Change in fair value	(13,460)	(13,460)	—	—
Fair value, at December 31, 2022	21,636	21,636	—	—
Fair value at issuance	49,534	—	23,698	25,836
Change in fair value	47,600	(4,545)	26,260	25,885
Fair value, at December 31, 2023	118,770	17,091	49,958	51,721
Warrant exercises	(90,240)	—	(46,083)	(44,157)
Change in fair value	(19,955)	(17,091)	(103)	(2,761)
Fair value, at December 31, 2024	$ 8,575	$ —	$ 3,772	$ 4,803

Warrant Exercises

The following table summarizes warrant exercise activity during the years ended December 31, 2024, 2023, and 2022:

	Total	December 2022 Warrants	February 2023 Warrants	July 2023 Warrants
Warrants issued, December 12, 2022	9,090,909	9,090,909	—	—
Warrant exercises	—	—	—	—
Warrants outstanding, at December 31, 2022	9,090,909	9,090,909	—	—
Warrant exercises	—	—	—	—
Warrant issuances	28,641,911	—	14,072,615	14,569,296
Warrants outstanding, at December 31, 2023	37,732,820	9,090,909	14,072,615	14,569,296
Warrant exercises	(22,242,740)	—	(11,258,092)	(10,984,648)
Warrant expirations	(9,090,909)	(9,090,909)	—	—
Warrants outstanding, at December 31, 2024	6,399,171	—	2,814,523	3,584,648

Warrant Valuation Assumptions

The estimated fair value of the warrants was computed using the Black-Scholes option pricing model with the following unobservable assumptions at the following dates:

	December 2022 Warrants			February and July 2023 Warrants	
	December 31, 2024	December 31, 2023	December 31, 2022	December 31, 2024	December 31, 2023
Exercise price per share	—	$6.60	$6.60	$3.2946	$3.2946
Expected term	—	1.0 year	2.0 years	1.6 years	2.6 years
Expected average volatility	—	119.0 %	99.4 %	125.0 %	107.3 %
Expected dividend yield	—	—	—	—	—
Risk-free interest rate	—	4.7 %	4.4 %	4.2 %	4.1 %

The expected term is the time remaining until the expiration of the warrants. The expected average volatility was estimated based on the historical and implied volatility of our common stock. The expected dividend yield was based on our expectation of not paying dividends for the foreseeable future. The risk-free interest rate was based on the U.S. Treasury's rates for U.S. Treasury zero-coupon bonds with maturities similar to those of the expected term of the award being valued.

15. Stockholders' Deficit

Stock Authorized for Issuance

As of December 31, 2024, the company was authorized to issue up to 1,350,000,000 shares of its common stock, par value $0.0001 per share, and 20,000,000 shares of our preferred stock, par value $0.0001 per share. As of December 31, 2024, there were 852,904,340 shares of our common stock outstanding (excluding 163,800 shares held by a majority owned subsidiary of the company that are treated as treasury shares for accounting purposes).

Stock Repurchases

In 2015, the Board of Directors approved the 2015 Share Repurchase Program, which allows our CEO or CFO to repurchase on behalf of the company, from time to time in the open market or in privately negotiated transactions, up to $50.0 million of our outstanding shares of common stock, exclusive of any commissions, markups, or expenses. The timing and amounts of any purchases were and will continue to be based on market conditions and other factors, including price, regulatory requirements, and other corporate considerations. The 2015 Share Repurchase Program does not require the purchase of any minimum number of shares and may be suspended, modified, or discontinued at any time without prior notice. We have financed, and expect to continue to finance, the purchases with existing cash balances. Shares repurchased under this program are formally retired through approval of the Board of Directors upon repurchase.

During the years ended December 31, 2024, 2023 and 2022, no shares of our common stock were repurchased under the program. Since the program's inception, we have repurchased a total of 6,403,489 shares at a total cost of $31.7 million. As of December 31, 2024, $18.3 million remained authorized to use for share repurchases under the program.

Shelf Registration Statements

During 2023, we filed a $750.0 million shelf registration statement with the SEC on Form S-3 for the offering and sale of equity and equity-linked securities, including common stock, preferred stock, debt securities, depositary shares, warrants to purchase common stock, preferred stock or debt securities, subscription rights, purchase contracts, and units. During the year ended December 31, 2023, we sold shares our common stock and warrants valued at $184.4 million under the shelf. As of December 31, 2024 and 2023, we had $565.6 million available for use under this shelf.

In April 2024, we filed a shelf registration statement with the SEC on Form S-3ASR pursuant to which we may, from time to time, sell an indeterminate amount of our common stock, preferred stock, debt securities, depositary shares, warrants, subscription rights, purchase contracts, or units, and an associated prospectus related to the ATM. During December 2024, we sold 38,333,334 shares of our common stock at $3.00 per share under the shelf generating net proceeds of approximately $106.9 million.

Open Market Sale Agreement

In April 2021, we entered into the ATM under which we may offer and sell, from time to time at our sole discretion, shares of our common stock through our sales agent. We pay our sales agent a commission of up to 3.0% of the gross sales proceeds of any shares of our common stock sold through them under the ATM and also have provided them with customary indemnification and contribution rights. During the years ended December 31, 2024, 2023 and 2022, we received net proceeds of approximately $3.6 million, $16.1 million, and $13.1 million, respectively, from the issuance of shares under the ATM.

We are not obligated to sell any shares and may at any time suspend solicitation and offers under the ATM. The ATM may be terminated by us at any time given written notice to the sales agent for any reason or by the sales agent at any time by giving written notice to us for any reason or immediately under certain circumstances and shall automatically terminate upon the issuance and sale of all of the shares.

Registered Direct Offerings

2023 Offerings

February 2023

On February 15, 2023, we entered into a securities purchase agreement with certain institutional investors for the purchase and sale of 14,072,615 shares of our common stock, as well as warrants that allow such investors to purchase an additional 14,072,615 shares of common stock at an exercise price of $4.2636 per share, for a purchase price of $3.5530 per share and accompanying warrant. This transaction generated net proceeds of approximately $47.0 million, after deducting placement agent fees and other offering costs of $3.0 million, of which $2.0 million was allocated to the sale of our common stock and recorded in *additional paid-in capital,* on the consolidated statement of stockholders' deficit during the year ended December 31, 2023. The warrants became immediately exercisable on February 17, 2023.

On July 25, 2023, pursuant to the terms of a letter amendment, the company and the investors agreed to reduce the exercise price of the outstanding February 2023 Warrants from $4.2636 per share to $3.2946 per share and extend the expiration date of the warrants to July 24, 2026. See Note 14 *"Warrant Liabilities"* for more information.

July 2023

On July 20, 2023, we entered into a securities purchase agreement with certain institutional investors for the purchase and sale of 14,569,296 shares of our common stock, as well as warrants that allow such investors to purchase an additional 14,569,296 shares of common stock at an exercise price of $3.2946 per share, for a purchase price of $2.7455 per share and accompanying warrant. This transaction generated net proceeds of approximately $37.5 million, after deducting placement agent fees and other estimated offering costs of $2.5 million, of which $12.7 million was allocated to the sale of our common stock and recorded in *additional paid-in capital*, on the consolidated statement of stockholders' deficit during the year ended December 31, 2023. The warrants became immediately exercisable on July 25, 2023 and expire on July 24, 2026.

2022 Offering

On December 12, 2022, we entered into a securities purchase agreement with an institutional investor for the sale of 9,090,909 shares of our common stock, as well as warrants that allow such investor to purchase an additional 9,090,909 shares of common stock at an exercise price of $6.60 per share, for a purchase price of $5.50 per share and accompanying warrant. This transaction generated net proceeds of approximately $47.0 million, after deducting placement agent fees and other offering costs of $3.0 million, of which $1.9 million was allocated to the sale of our common stock and recorded in *additional-paid-in capital,* on the consolidated statement of stockholders' deficit during the year ended December 31, 2022.

Exercises of Warrants

During the year ended December 31, 2024, institutional holders exercised a total of 11,258,092 warrants pursuant to the February 2023 Warrant agreement at an exercise price of $3.2946 per share resulting in the issuance of 11,258,092 shares of the company's common stock for proceeds totaling $37.1 million. We recorded $83.2 million in *additional paid-in capital,* on the consolidated statement of stockholders' deficit during the year ended December 31, 2024 related to these exercises of warrants.

During the year ended December 31, 2024, institutional holders exercised a total of 10,984,648 warrants pursuant to the July 2023 Warrant agreement at an exercise price of $3.2946 per share resulting in the issuance of 10,984,648 shares of the company's common stock for proceeds totaling $36.2 million. We recorded $80.3 million in *additional paid-in capital,* on the consolidated statement of stockholders' deficit during the year ended December 31, 2024 related to these exercises of warrants.

Stock Purchase and Option Agreement

On December 29, 2023 and in connection with the RIPA, we entered into an SPOA with Oberland. Under this agreement, Oberland had an option to purchase up to $10.0 million of our common stock, at a price per share to be determined by reference to the 30-day trailing volume weighted-average price of our common stock, calculated from the date of exercise. The option is exercisable by Oberland any time until the earliest of (i) December 29, 2028, (ii) a change of control of the company, or (iii) a sale of substantially all of the company's assets. Among other limitations, the option may only be exercised to the extent that the common stock issuable pursuant to such exercise would not exceed 19.9% of the common stock outstanding immediately after giving effect to such exercise.

Pursuant to the SPOA, in April 2024 Oberland exercised its option to purchase 858,990 shares of our common stock at an exercise price of $5.8208 per share generating net proceeds of approximately $4.9 million. In relation to this transaction, we recorded $7.6 million in *additional paid-in capital,* on the statement of stockholders' deficit during the year ended December 31, 2024. Following such exercise, approximately $5.0 million remains available for future exercise under the SPOA as of December 31, 2024.

Conversion of Promissory Notes into Common Stock

In connection with our December 2024 equity offering, the company received written notice from Nant Capital, the holder of the $30.0 million promissory note due December 31, 2025, of its election to convert the entire outstanding principal and accrued interest under the existing note into shares of the company's common stock. As of such date, the total outstanding principal amount and accrued and unpaid interest due under the existing note of approximately $30.7 million were converted into 13,475,172 shares of the company's common stock at a price of $2.28 per share in accordance with the terms of the promissory note. We recorded a net increase of $26.2 million in *additional paid-in capital*, on the consolidated balance sheet related to this transaction. See Note 12 *"Related-Party Debt"* for more information.

Also, in connection with our December 2024 equity offering, the company received written notice from Nant Capital, the holder of the $200.0 million promissory note due September 11, 2026, of its election to convert the entire outstanding principal and accrued interest under the existing note into shares of the company's common stock. As of such date, the total outstanding principal amount and accrued and unpaid interest due under the existing note of approximately $200.7 million were converted into 103,710,088 shares of the company's common stock at a price of $1.9350 per share in accordance with the terms of the promissory note. We recorded a net increase of $162.3 million in *additional paid-in capital*, on the consolidated balance sheet related to this transaction. See Note 12 *"Related-Party Debt"* for more information.

On September 11, 2023, the company entered into a stock purchase agreement with Nant Capital, NantMobile and NCSC pursuant to which the related-party purchasers exchanged all such fixed-rate promissory notes, representing approximately $270.0 million in aggregate principal amount and accrued and unpaid interest, in exchange for an aggregate of 209,291,936 shares of common stock at an exchange price of $1.29 per share.

On December 12, 2022, the company received written notice from NantWorks, the holder of the existing note, of its election to convert the entire outstanding principal and accrued and unpaid interest under the existing note into shares of the company's common stock. As of such date, the entire outstanding principal amount and accrued and unpaid interest due under the existing note of approximately $56.6 million and an unamortized debt discount of $4.7 million were converted into 9,986,920 shares of the company's common stock at a price of $5.67 per share in accordance with the terms of the existing note. We recorded a net increase of $51.9 million in *additional paid-in capital,* on the consolidated balance sheet related to this transaction.

16. Stock-Based Compensation

2015 Equity Incentive Plan

In 2015, the Board of Directors adopted, and our stockholders approved, the 2015 Plan. The 2015 Plan, as amended, permits the grant of incentive stock options to the company's employees, and the grant of non-statutory stock options, restricted stock, RSUs, stock appreciation rights, performance units and performance shares to the company's employees, directors, and consultants. In addition, the number of shares reserved for future grant under the 2015 Plan include shares subject to stock options granted under the 2014 Plan that expire or terminate without having been exercised in full and shares issued pursuant to awards granted under the 2014 Plan that are forfeited to or repurchased by us (provided that the maximum number of shares that may be added to the 2015 Plan pursuant to this provision is approximately 110,020 shares as of December 31, 2024).

As of December 31, 2024, the 2015 Plan is the only equity plan available for grant of equity awards to employees, directors, and consultants of the company. As of December 31, 2024, approximately 25.4 million shares were available for future grants under the 2015 Plan.

Stock-Based Compensation

The following table presents stock-based compensation included on the consolidated statements of operations (in thousands):

	Year Ended December 31,		
	2024	2023	2022
Stock-based compensation expense:			
Stock options	$ 15,679	$ 13,884	$ 13,280
RSUs	18,753	35,279	26,899
	$ 34,432	$ 49,163	$ 40,179
Stock-based compensation expense in operating expenses:			
Research and development	$ 12,005	$ 17,341	$ 11,669
Selling, general and administrative	22,427	31,822	28,510
	$ 34,432	$ 49,163	$ 40,179

Stock Options

The following table summarizes stock option activity and related information for the year ended December 31, 2024:

	Number of Options	Weighted-Average Exercise Price	Aggregate Intrinsic Value (in thousands)	Weighted-Average Remaining Contractual Life (in years)
Outstanding as of December 31, 2023	9,820,435	$ 9.46	$ 6,046	6.6
Granted	6,336,675	$ 5.29		
Exercised	(308,959)	$ 2.31		
Expired/forfeited	(440,563)	$ 5.48		
Outstanding as of December 31, 2024	15,407,588	$ 8.00	$ 90	7.1
Vested and exercisable as of December 31, 2024	8,038,537	$ 10.39	$ 90	5.5

As of December 31, 2024, the unrecognized compensation cost related to outstanding stock options was $20.1 million, which is expected to be recognized over a remaining weighted-average period of 1.7 years.

During the year ended December 31, 2024, 2023 and 2022, the total intrinsic value of stock options exercised was $0.9 million, $0.3 million, and immaterial, respectively. During the years ended December 31, 2024, 2023 and 2022, cash proceeds received from stock option exercises were $0.7 million, $0.3 million, and $0.1 million, respectively.

As of December 31, 2023, a total of 5,867,252 vested and exercisable stock options were outstanding.

The fair value of stock options issued was estimated at the date of grant using the Black-Scholes option pricing model with the following weighted-average assumptions:

	Year Ended December 31,		
	2024	2023	2022
Expected term	5.96 years	5.50 years	5.69 years
Risk-free interest rate	4.3 %	4.0%	2.6 %
Expected volatility	116.8 %	116.2%	101.8 %
Dividend yield	— %	—%	— %
Weighted-average grant date fair value	$4.58	$2.53	$4.20

The expected term was estimated using the average of the contractual term and the weighted-average vesting term of the options. The risk-free interest rate was based on the U.S. Treasury's rates for U.S. Treasury zero-coupon bonds with maturities similar to those of the expected term of the award being valued. The expected volatility was estimated based on the historical volatility of our common stock. The assumed dividend yield was based on our expectation of not paying dividends for the foreseeable future.

Restricted Stock Units

The following table summarizes RSU activity during the year ended December 31, 2024:

	Number of Units	Weighted-Average Grant Date Fair Value
Nonvested balance as of December 31, 2023	7,503,979	$ 12.01
Granted	3,323,868	$ 4.77
Vested	(4,269,864)	$ 7.11
Forfeited/canceled	(612,562)	$ 12.76
Nonvested balance as of December 31, 2024	5,945,421	$ 11.41

As of December 31, 2024, there was $27.3 million of unrecognized stock-based compensation expense related to RSUs that is expected to be recognized over a weighted-average period of 1.9 years. During the years ended December 31, 2024, 2023 and 2022, the total fair value of RSUs vested was $14.6 million, $11.1 million, and $2.6 million, respectively.

Effective as of August 25, 2023, the Compensation Committee of the Board of Directors granted 5,727,159 RSUs to eligible employees of the company, with the intention of retaining such employees (the "retention award"). The retention award vests according to the following schedule: ½ (one-half) was to vest and vested on September 1, 2023 and ½ (one-half) on January 31, 2024, subject to the recipients continuing to be a "service provider" (as defined in the 2015 Plan) through each applicable vesting date. With respect to RSUs granted, compensation cost was measured using the grant date fair value of $1.65 per share, the closing price of the company's common stock on August 25, 2023.

RSUs awarded to employees and consultants of affiliated companies are accounted for as stock-based compensation in accordance with ASU 2018-07, *Compensation—Stock Compensation (Topic 718)*, as the compensation was in exchange for continued support or services expected to be provided to the company over the vesting periods under the NantWorks shared services agreement discussed in Note 13 *"Related-Party Agreements."* We have evaluated the associated benefit of these awards to the affiliated companies under common control and determined that the benefit is limited to the retention of their employees. We estimated such benefit at the grant date fair value of $4.0 million. During the year ended December 31, 2024, We recorded deemed dividends of $0.2 million during the year ended December 31, 2024 and $0.4 million during the years ended December 31, 2023 and 2022, respectively, in *additional paid-in capital,* on the consolidated balance sheets, with a corresponding credit to stock-based compensation expense.

Related-Party Warrants

A total of 1,638,000 warrants issued to an affiliate of Dr. Soon-Shiong with an exercise price of $3.24 per share were outstanding as of December 31, 2024. The fair value of $18.0 million assigned to the warrants will be recognized in equity upon achievement of a performance-based vesting condition pertaining to building manufacturing capacity to support supply requirements for ANKTIVA (which has not yet been satisfied). The warrants become exercisable 30 days following the achievement of the performance-based vesting condition (the "initial exercise date") and expire on the 10th anniversary of the initial exercise date.

17. Income Taxes

We are subject to U.S. federal income tax, as well as income tax in Italy, South Korea, California, and other states. From inception through December 31, 2024, we have not been required to pay U.S. federal and state income taxes because of current and accumulated NOLs. Our federal returns for tax years 2021 through 2023 remain open to examination, and our state returns remain subject to examination for tax years 2020 through 2023. The Italian and South Korean returns for tax years 2019 through 2023 remain open to examination. Carryforward attributes that were generated in years where the statute of limitations is closed may still be adjusted upon examination by the IRS or other respective tax authorities. No income tax returns are currently under examination by taxing authorities. There are no cumulative earnings in our Italian and South Korean subsidiaries as of December 31, 2024 that would be subject to U.S. income tax or foreign withholding tax. We plan to indefinitely reinvest any future earnings of our foreign subsidiaries.

Our loss before income taxes is as follows (in thousands):

	Year Ended December 31,		
	2024	2023	2022
U.S. loss before income taxes	$ (410,458)	$ (581,136)	$ (413,653)
Foreign loss before income taxes	(3,187)	(2,756)	(3,633)
Loss before income taxes	$ (413,645)	$ (583,892)	$ (417,286)

Income tax (expense) benefit consists of the following (in thousands):

	Year Ended December 31,		
	2024	2023	2022
Current:			
Federal	$ —	$ —	$ —
State	—	26	(38)
Foreign	—	—	—
Total current	—	26	(38)
Deferred:			
Federal	—	5	2
State	—	9	2
Foreign	—	—	—
Total deferred	—	14	4
Total income tax (expense) benefit	$ —	$ 40	$ (34)

The components that comprise our net deferred tax liabilities consist of the following (in thousands):

	As of December 31,	
	2024	2023
Deferred tax assets:		
Net operating loss carryforwards	$ 475,130	$ 420,782
Section 174 R&E capitalization	111,598	87,721
Interest expense	69,681	39,859
Research and development credits	68,070	56,610
Stock-based compensation	20,799	22,554
Operating lease liabilities	10,886	11,605
Valuation discount	6,641	9,095
Other	32,604	34,496
Total deferred tax assets	795,409	682,722
Deferred tax liabilities:		
Debt discount	(9,735)	(23,365)
Operating lease right-of-use assets	(8,589)	(9,380)
Depreciation	—	(1,533)
Indefinite-lived intangible assets	(139)	(148)
Total deferred tax liabilities	(18,463)	(34,426)
Net deferred tax assets	776,946	648,296
Valuation allowance	(777,085)	(648,444)
Net deferred tax liabilities	$ (139)	$ (148)

As of December 31, 2024, we have federal NOLs of $1.8 billion, state NOLs of $2.1 billion, and foreign NOLs of $16.3 million. Of the $1.8 billion in federal NOLs, $1.4 billion do not expire and will be able to be used to offset 80% of taxable income in future years. Of the $2.1 billion in state NOLs, $64.3 million do not expire and will be able to be used to offset 80% of taxable income in future years. The remaining federal NOL carryforwards expire beginning in 2025, the remaining state NOL carryforwards expire beginning in 2025, the South Korean NOL carryforwards expire beginning in 2025, and the Italian NOLs do not expire.

In assessing the realization of deferred tax assets, management considers whether it is more likely than not that some or all of our deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Management considers the scheduled reversal of deferred tax liabilities, projected future taxable income and tax planning strategies in making this assessment. Based on the level of historical operating results and the uncertainty of economic conditions, we recorded a valuation allowance of $777.1 million and $648.4 million as of December 31, 2024 and 2023, respectively. During the years ended December 31, 2024 and 2023, the valuation allowance increased by $128.7 million and $156.6 million, respectively, which was mainly driven by losses from which we cannot benefit. The portion of the valuation allowance for deferred tax assets for which subsequently recognized tax benefits will be credited directly to contributed capital is $0.2 million.

A reconciliation of the federal statutory income tax rate to our effective income tax rate is as follows:

	Year Ended December 31,		
	2024	2023	2022
Federal statutory tax rate	21.0 %	21.0 %	21.0 %
State income taxes, net of federal tax benefit	5.2 %	6.8 %	9.5 %
Change in fair value of warrants	1.0 %	(1.8)%	0.5 %
Change in fair value of convertible notes	2.2 %	(1.3)%	— %
Investment loss	— %	2.1 %	— %
Other permanent items	— %	— %	(0.1)%
Tax rate adjustment	3.9 %	1.4 %	(0.4)%
Research and development credits	2.5 %	3.1 %	3.6 %
Stock-based compensation	(1.1)%	(1.0)%	(0.5)%
Section 162(m) limitation	(0.5)%	(0.4)%	(2.1)%
Other	(4.5)%	0.3 %	1.5 %
Valuation allowance	(29.7)%	(30.2)%	(33.0)%
Effective income tax rate	— %	— %	— %

Pursuant to Sections 382 and 383 of the Code, annual use of our net operating loss and research and development credit carryforwards may be limited in the event a cumulative change in ownership of more than 50% occurs within a three-year period. We have not recognized the deferred tax assets for federal and state NOLs and credits of $266.5 million from our deferred tax asset schedules as of December 31, 2024 due to Section 382/383 limitations. There is no impact to tax expense for the derecognition of net operating losses, and federal and state research and development credits due to the valuation allowance recorded against our deferred tax assets.

As of December 31, 2024, we also had federal research tax credit carryforwards of $55.6 million and state research tax credits of $35.7 million. The federal research tax credit carryforwards expire beginning in 2032 and certain state research tax credit carryforwards expire beginning in 2030. Our California research tax credits can be carried forward indefinitely. As of December 31, 2024, we also had federal other tax credits carryforwards of $1.3 million and the tax credit carryforwards expire beginning in 2036.

Net operating losses and tax credits also are limited when there is a SRLY. These rules generally limit the use of the acquired or departing members' net operating loss and tax credit carryovers to the amount of taxable income such entity contributes to consolidated taxable income. The 80% limitation also applies to SRLY NOL carryovers and tax credits. Therefore, any SRLY NOLs and tax credits will be subject to this limitation, as well as Section 382 and 383 limitations.

As of December 31, 2024 and 2023, we have $287.5 million and $164.6 million of interest, respectively, that is temporarily disallowed pursuant to Section 163(j) of the Code. This interest can be carried forward indefinitely and will be deductible when the company generates sufficient adjusted taxable income.

A summary of changes to the amount of unrecognized tax benefits is as follows (in thousands):

	Year Ended December 31,		
	2024	2023	2022
Unrecognized tax benefits, beginning of year	$ 35,470	$ 16,252	$ 13,504
Additions based on tax positions related to the current year	1,251	18,976	1,710
Additions based on tax positions related to prior years	—	242	1,038
Reductions for tax positions of prior years	(2,178)	—	—
Unrecognized tax benefits, end of year	$ 34,543	$ 35,470	$ 16,252

Included in the balance of unrecognized tax benefits as of December 31, 2024 is $16.4 million that, if recognized, would not impact our income tax benefit or effective tax rate as long as the deferred tax asset remains subject to a full valuation allowance. We do not expect that the unrecognized tax benefits will change within 12 months of December 31, 2024. Due to the existence of the valuation allowance, future changes in our unrecognized tax benefits will not impact our effective tax rate. We have not incurred any material interest or penalties as of the current reporting date with respect to income tax matters.

Inflation Reduction Act of 2022

The IRA, which incorporates a corporate alternative minimum tax, was signed on August 16, 2022. The changes are effective for the tax years beginning after December 31, 2022. The new tax will require companies to compute two separate calculations for federal income tax purposes and pay the greater of the new minimum tax or their regular tax liability. The company is not an applicable corporation for the year ended December 31, 2024.

18. Employee Benefits

Defined Contribution Plan

In December 2015, we adopted a 401(k) Plan covering all employees. The 401(k) Plan allows employees to make pre- and post-tax contributions up to the maximum allowable amount set by the IRS. The company, at its discretion, may make certain contributions to the 401(k) Plan. During the years ended December 31, 2024, 2023 and 2022, we made contributions totaling $3.0 million, $2.8 million, and $2.7 million, respectively, to the 401(k) Plan.

Compensated Absences

Under our vacation policy, salaried employees are provided unlimited vacation leave. Therefore, we do not record an accrual for paid leave related to these employees since we are unable to reasonably estimate the compensated absences that these employees will take.

19. Segment Information

We operate in one business segment, and therefore have one reportable segment, focused on developing next-generation therapies that bolster the natural immune system while addressing serious unmet needs within urologic and other cancers as well as infectious diseases. Our CEO is the chief operating decision-maker of the company and manages and allocates resources to our operations on a company-wide basis. Consistent with this decision-making process, our CEO uses consolidated, single-segment financial information for purposes of evaluating performance, forecasting future-period financial results, allocating resources, and setting incentive targets. The measure of segment performance is net income (loss) as reflected in the consolidated statement of operations. The CODM uses net income (loss) to allocate resources on a consolidated basis, which enables the CODM to assess both the overall level of resources available and optimize distribution of resources across functions, therapeutic areas, regions and research and development programs in line with our long-term corporate-wide strategic goals. As the company manages its assets on a consolidated basis, the measure of segment assets is total assets, as reflected in the consolidated balance sheet.

Net loss for our segment is as follows (in thousands):

	Year Ended December 31,		
	2024	2023	2022
Revenue			
Product revenue, net	$ 14,150	$ —	$ —
Other revenues	595	622	240
Total revenue	14,745	622	240
Operating costs and expenses			
Cost of sales	—	—	—
Research and development – external (including amounts with related parties) (1)	29,268	67,124	61,807
Research and development – internal (including amounts with related parties) (2)	160,876	165,242	186,342
Selling, general and administrative expense (including amounts with related parties)	168,783	129,620	102,708
Impairment of intangible assets	—	886	681
Other segment items (3)	69,463	221,602	66,022
Total operating costs and expenses	428,390	584,474	417,560
Net loss	$ (413,645)	$ (583,852)	$ (417,320)

(1) Our external research and development expenses support our various preclinical and clinical programs.

(2) Our internal research and development expenses include payroll and benefits expenses, facilities and equipment expense, and other indirect research and development expenses incurred in support of its research and development activities.

(3) Other segment items include interest and investment income (loss), net; interest expense (including amounts with related parties); changes in the fair value of warrant liabilities, related-party convertible notes and derivative liabilities; interest expense related to revenue interest liability; loss on equity method investment; other (expense) income, net (including amounts with related parties); and income tax benefit (expense).

We generate a portion of our revenues from outside of the U.S. Information about our revenue by geographic region is as follows (in thousands):

	Year Ended December 31,		
	2024	2023	2022
U.S.	$ 14,214	$ 31	$ 42
Europe	531	591	198
Total segment revenue	$ 14,745	$ 622	$ 240

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

Our disclosure controls and procedures are designed to provide reasonable assurance of achieving their objectives of ensuring that information we are required to disclose in the reports we file or submit under the Exchange Act is accumulated and communicated to our management, including our CEO and CFO, as appropriate, to allow timely decisions regarding required disclosures, and is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. There is no assurance that our disclosure controls and procedures will operate effectively under all circumstances.

Management, with the participation of our CEO and CFO, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2024. The term "disclosure controls and procedures" (as defined in Rule 13a-15(e) of the Exchange Act) means controls and other procedures of a company that are designed to provide reasonable assurance that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to provide reasonable assurance that information required to be disclosed is accumulated and communicated to our management, including our CEO and CFO, as appropriate, to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their desired control objectives, and management necessarily is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of December 31, 2024, our CEO and CFO have concluded that, as of December 31, 2024, our disclosure controls and procedures were effective at the reasonable assurance level.

Management's Report on Internal Control Over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting as such term is defined in Rule 13a-15(f) under the Exchange Act. Internal control over financial reporting is a process designed under the supervision and with the participation of our management, including our CEO and CFO, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. Our internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of our assets; and (ii) provide reasonable assurance (a) that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, (b) that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and (c) regarding the prevention or timely detection of the unauthorized acquisition, use or disposition of assets that could have a material effect on our financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, 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.

As of December 31, 2024, our management conducted an evaluation of the effectiveness of our internal control over financial reporting using the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control – Integrated Framework (2013). Based on this evaluation, our management concluded that, as of December 31, 2024, our internal control over financial reporting was effective.

Attestation Report of the Registered Public Accounting Firm

The effectiveness of the company's internal control over financial reporting has been audited by Ernst & Young LLP, our independent registered public accounting firm, as stated in its attestation report appearing on page 232 of this Annual Report under the heading "Report of Independent Registered Public Accounting Firm," which expresses an unqualified opinion concerning the effectiveness of the company's internal control over financial reporting as of December 31, 2024.

Changes in Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act) during the fiscal quarter ended December 31, 2024, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on Effectiveness of Controls

Management recognizes that a control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud or error, if any, have been detected. These inherent limitations include the realities that judgments in decision making can be faulty, and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by management override of the controls. The design of any system of controls also 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 the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of ImmunityBio, Inc. and Subsidiaries

Opinion on Internal Control Over Financial Reporting

We have audited ImmunityBio, Inc. and Subsidiaries' internal control over financial reporting as of December 31, 2024, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). In our opinion, ImmunityBio, Inc. and Subsidiaries (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2024, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of the Company as of December 31, 2024 and 2023, the related consolidated statements of operations, comprehensive loss, stockholders' deficit and cash flows for each of the three years in the period ended December 31, 2024, and the related notes and our report dated March 3, 2025 expressed an unqualified opinion thereon.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the 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 audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects.

Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control Over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) 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. Also, 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.

/s/ Ernst & Young LLP

Los Angeles, California
March 3, 2025

ITEM 9B. OTHER INFORMATION.

(a) None.

(b) Adoption and Termination (including Modification) of Rule 10b5-1 and Certain Other Trading Arrangements by Directors and Officers

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

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS.

Not applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE.

The information required by this item will be contained in our definitive proxy statement to be filed with the SEC on Schedule 14A in connection with our Proxy Statement, which is expected to be filed not later than 120 days after the end of our fiscal year ended December 31, 2024, and is incorporated herein by reference.

ITEM 11. EXECUTIVE COMPENSATION.

The information required by this item will be contained in the Proxy Statement under the headings "Executive Compensation," "Executive Compensation Tables," and "Director Compensation," and is incorporated herein by reference.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS.

The information required by this item will be contained in the Proxy Statement under the headings "Security Ownership of Certain Beneficial Owners and Management" and "Equity Compensation Plan Information," and is incorporated herein by reference.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE.

The information required by this item will be contained in the Proxy Statement under the headings "Certain Relationships and Related-Party Transactions" and "Corporate Governance," and is incorporated herein by reference.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES.

The information required by this item will be contained in the Proxy Statement under the heading "Fees Paid to Independent Registered Public Accounting Firm" and is incorporated herein by reference.

PART IV

ITEM 15. EXHIBIT AND FINANCIAL STATEMENT SCHEDULES.

The consolidated financial statements, financial statement schedules and exhibits filed as part of this Annual Report are as follows:

(1) Financial Statements

Reference is made to the consolidated financial statements identified in the "Index to Financial Statements" under Part II, Item 8. "Financial Statements and Supplementary Data" of this Annual Report.

(2) Financial Statement Schedules for the Years Ended December 31, 2024, 2023 and 2022

All financial statement schedules have been omitted because the information required to be set forth therein is not applicable or is otherwise included in the consolidated financial statements or notes thereto. See Part II, Item 8. *"*Financial Statements and Supplementary Data*"* of this Annual Report.

(3) Exhibits

The documents listed below are incorporated by reference or filed or furnished with this Annual Report, in each case as indicated therein (numbered in accordance with Item 601 of Regulation S-K).

Exhibit Number	Description	Incorporated by Reference Herein			
		Form	File No.	Exhibit No.	Filing Date
3.1	Amended and Restated Certificate of Incorporation of ImmunityBio, Inc.	8-K	001-37507	3.1	August 4, 2015
3.2	Certificate of Amendment of Amended and Restated Certificate of Incorporation of ImmunityBio, Inc. dated March 9, 2021.	8-K	001-37507	3.1	March 10, 2021
3.3	Certificate of Amendment of Amended and Restated Certificate of Incorporation of ImmunityBio, Inc. dated February 1, 2022.	POSASR	333-255699	3.3	March 1, 2022
3.4	Certificate of Amendment of Amended and Restated Certificate of Incorporation of ImmunityBio, Inc. dated October 18, 2023.	10-Q	001-37507	3.4	November 9, 2023
3.5	Amended and Restated Bylaws of ImmunityBio, Inc. effective as of March 10, 2021.	10-Q	001-37507	3.2	August 12, 2021
4.1	Nominating Agreement by and between the Registrant and Cambridge Equities, LP, dated June 18, 2015.	S-1	333-205124	4.1	June 19, 2015
4.2	Form of Registration Rights Agreement by and between the Registrant and the Purchasers of Common Stock, dated June 2015.	S-1	333-205124	4.2	June 19, 2015
4.3	Registration Rights Agreement by and between the Registrant and Cambridge Equities, LP, dated December 23, 2014.	S-1	333-205124	4.3	June 19, 2015
4.4	Form of Subscription and Securities Purchase Agreement among the Registrant and the Subscribers of Series C Preferred Stock, dated as of April 1, 2014.	S-1	333-205124	4.5	June 19, 2015

Exhibit Number	Description	Incorporated by Reference Herein			
		Form	File No.	Exhibit No.	Filing Date
4.5	Registration Rights Agreement, among the Registrant and the purchasers of Series B Preferred Stock, dated as of June 20, 2013.	S-1	333-205124	4.6	June 19, 2015
4.6	Specimen Common Stock Certificate.	S-8 POS	333-252232	4.1	May 21, 2021
4.7	Description of Registrant's Securities.	10-K	001-37507	4.7	March 19, 2024
4.8+	Common Stock Purchase Warrant, dated June 30, 2016, issued by the Company to NantWorks, LLC.	S-4	333-252232	10.13	January 19, 2021
4.9	Amended Form of February 2023 Common Stock Purchase Warrant.	10-Q	001-37507	4.1	November 9, 2023
4.10	Form of July 2023 Common Stock Purchase Warrant.	8-K	001-37507	4.1	July 21, 2023
10.1	Voting Agreement, dated as of December 21, 2020, by and among ImmunityBio, Inc., NantKwest, Inc. and the NantKwest, Inc. stockholders party thereto.	8-K	001-37507	10.1	December 22, 2020
10.2	Voting Agreement, dated as of December 21, 2020, by and among ImmunityBio, Inc., NantKwest, Inc. and the ImmunityBio, Inc. stockholders party thereto.	8-K	001-37507	10.2	December 22, 2020
10.3+	Revenue Interest Purchase Agreement dated as of December 29, 2023 among ImmunityBio, Inc., the Purchasers from time to time party hereto and Infinity SA LLC.	10-K	001-37507	10.3	March 19, 2024
10.4	Limited Consent and Amendment to Revenue Interest Purchase Agreement, dated as of December 10, 2024, by and between ImmunityBio, Inc., the Purchasers party thereto, and Infinity SA LLC, as Collateral Agent and Administrative Agent for the Purchasers.	8-K	001-37507	1.3	December 11, 2024
10.5+	Security and Pledge Agreement as of December 29, 2023 among ImmunityBio, Inc., the Subsidiary Guarantors listed on the signature pages hereto, such other parties that may become Grantors hereunder after the date hereof and Infinity SA LLC.	10-K	001-37507	10.4	March 19, 2024
10.6+	Stock Purchase and Option Agreement dated December 29, 2023 by and between the Investors and ImmunityBio, Inc.	10-K	001-37507	10.5	March 19, 2024
10.7	Securities Purchase Agreement dated as of July 20, 2023.	8-K	001-37507	10.1	July 21, 2023
10.8	Securities Purchase Agreement dated as of February 15, 2023.	8-K	001-37507	10.1	February 15, 2023

Exhibit Number	Description	Incorporated by Reference Herein			
		Form	File No.	Exhibit No.	Filing Date
10.9	Open Market Sale Agreement dated April 30, 2021, by and between ImmunityBio, Inc. and Jefferies LLC.	8-K	001-37507	10.1	May 3, 2021
10.10+	Agreement and Plan of Merger, dated May 19, 2017, by and among the Company, Altor Acquisition LLC, Altor BioScience Corporation and Shareholder Representative Services LLC.	S-4	333-252232	10.4	January 19, 2021
10.11	Sales Milestone Contingent Value Rights Agreement, dated as of July 31, 2017, by and between the Company and Shareholder Representative Services LLC.	S-4	333-252232	10.12	January 19, 2021
10.12	Second Amended and Restated Promissory Note by and between ImmunityBio, Inc. and Nant Capital, LLC, dated as of December 10, 2024.	8-K	001-37507	1.2	December 11, 2024
10.13	Lease Agreement by and between ARE-JOHN HOPKINS COURT, LLC and the Company, dated June 19, 2015.	S-1/A	333-205124	10.19	July 27, 2015
10.14	First Amendment to Lease dated July 16, 2015 by and between ARE-JOHN HOPKINS COURT, LLC and Conkwest, Inc.	10-Q	001-37507	10.6	August 8, 2022
10.15	Second Amendment to Lease effective as of June 18, 2016 by and between ARE-JOHN HOPKINS COURT, LLC and NantKwest, Inc., fka Conkwest, Inc.	10-Q	001-37507	10.7	August 8, 2022
10.16	Third Amendment to Lease dated April 12, 2022 by and between ARE-JOHN HOPKINS COURT, LLC and ImmunityBio, Inc.	10-Q	001-37507	10.8	August 8, 2022
10.17	Facility License Agreement by and between NantWorks, LLC and the Company, dated as of November 6, 2015.	10-K	001-37507	10.23	March 30, 2016
10.18	First Amendment to Facility License Agreement by and between NantWorks, LLC and the Company, dated as of September 14, 2020.	10-Q	001-37507	10.2	November 9, 2020
10.19	Second Amendment to Facility License Agreement, effective as of May 1, 2022, by and between NantWorks, LLC, the Licensor, and ImmunityBio, Inc., the Licensee.	10-Q	001-37507	10.4	August 8, 2022
10.20	Commercial Lease by and between 605 Doug St, LLC and the Company, dated September 15, 2016.	10-Q	001-37507	10.1	November 10, 2016
10.21	Extension of Commercial Lease by and between 605 Doug St, LLC and ImmunityBio, Inc., dated June 30, 2023.	10-Q	001-37507	10.2	August 8, 2023

Exhibit Number	Description	Incorporated by Reference Herein			
		Form	File No.	Exhibit No.	Filing Date
10.22+	Commercial Lease by and between Duley Road, LLC and Altor BioScience Manufacturing Company, LLC, dated February 1, 2017.	S-4	333-252232	10.27	January 19, 2021
10.23	Extension of Commercial Lease by and between Duley Road, LLC and Altor BioScience Manufacturing Company, LLC, dated October 3, 2023.	10-K	001-37507	10.41	March 19, 2024
10.24+	Commercial Lease by and between Duley Road, LLC and the Company, dated January 28, 2019.	S-4	333-252232	10.28	January 19, 2021
10.25+	Commercial Lease by and between Duley Road, LLC and the Company, dated January 28, 2019.	S-4	333-252232	10.29	January 19, 2021
10.26	Sublease Agreement between Altor BioScience Manufacturing Company, LLC and the Company, dated as of September 30, 2020.	10-Q	001-37507	10.3	November 9, 2020
10.27	Commercial Lease between 605 Nash, LLC and the Company, dated February 11, 2021.	10-K	001-37507	10.35	March 4, 2021
10.28	First Amendment to Lease (Expansion & Extension) made and entered into as of May 28, 2021 by and between 605 Nash, LLC and ImmunityBio, Inc.	10-Q	001-37507	10.1	August 12, 2021
10.29	Commercial Lease Agreement dated September 27, 2021 by and between 420 Nash, LLC and ImmunityBio, Inc.	10-Q	001-37507	10.4	November 12, 2021
10.30	Fort Schuyler Management Corporation Lease, effective as of October 1, 2021, between Fort Schuyler Management Corporation, as Landlord, and Athenex, Inc., as Tenant.	10-Q	001-37507	10.2	May 10, 2022
10.31	First Amendment to Lease, effective as of February 14, 2022, by and among Fort Schuyler Management Corporation and ImmunityBio, Inc.	10-Q	001-37507	10.3	May 10, 2022
10.32+	Purchase Agreement by and between Athenex, Inc. and ImmunityBio, Inc. dated January 7, 2022.	8-K	001-37507	10.1	January 12, 2022

Exhibit Number	Description	Incorporated by Reference Herein			
		Form	File No.	Exhibit No.	Filing Date
10.33+	Letter Agreement effective as of July 1, 2019 between Immuno-Oncology Clinic, Inc. and the Company.	10-Q	001-37507	10.4	August 6, 2019
10.34	First Amendment to the July 1, 2019 Letter Agreement by and between Immuno-Oncology Clinic, Inc. and the Company, dated March 31, 2020.	10-Q	001-37507	10.1	May 11, 2020
10.35	Amended and Restated Shared Services Agreement by and between NantKwest, Inc. and NantWorks, LLC, dated June 28, 2016.	10-Q	001-37507	10.1	August 15, 2016
10.36#+	Offer Letter between the Company and Richard Adcock, dated October 26, 2020.	10-Q	001-37507	10.4	November 9, 2020
10.3#7+	Offer Letter, dated August 3, 2020, between ImmunityBio, Inc. and David Sachs.	S-4	333-252232	10.31	January 19, 2021
10.38	Form of Indemnification Agreement between ImmunityBio, Inc. and each of its Directors and Executive Officers.	S-1	333-205124	10.1	June 19, 2015
10.39#	Executive Incentive Compensation Plan.	S-1/A	333-205124	10.4	July 15, 2015
10.40#	2014 NantKwest, Inc. Equity Incentive Plan and forms of agreement thereunder.	S-1	333-205124	10.2	June 19, 2015
10.41#	ImmunityBio, Inc. 2015 Equity Incentive Plan.	10-Q	001-37507	10.1	August 12, 2024
10.42#	NantCell, Inc. 2015 Stock Incentive Plan and forms of agreement thereunder.	S-4	333-252332	10.14	January 19, 2021
10.43+	Settlement Agreement and Release dated July 13, 2024 entered into by and among Altor BioScience, LLC, NantCell, Inc., HCW Biologics, Inc., and Dr. Hing C. Wong.	10-Q	001-37507	10.1	November 12, 2024
19.1*	ImmunityBio, Inc. Insider Trading Policy, as Amended.				
21.1*	Subsidiaries of ImmunityBio, Inc. as of December 31, 2024.				
23.1*	Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm.				
24.1*	Power of Attorney (Contained in Signature Page to this Annual Report).				
31.1*	Certification of Principal Executive Officer pursuant to Exchange Act Rules 13a-14(a) and 15(d)-14(a) of the Securities Act, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				

Exhibit Number	Description	Incorporated by Reference Herein			
		Form	File No.	Exhibit No.	Filing Date
31.2*	Certification of Principal Financial Officer pursuant to Exchange Act Rules 13a-14(a) and 15(d)-14(a) of the Securities Act, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
32.1**	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
32.2**	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
97.1#+	ImmunityBio, Inc. Compensation Recovery Policy as adopted or most recently updated on November 29, 2023.	10-K	001-37507	97.1	March 19, 2024
101.INS	Inline XBRL Instance Document (the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document).				
101.SCH	Inline XBRL Taxonomy Extension Schema Document.				
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.				
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.				
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.				
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.				
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).				

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* Filed herewith.

** The certifications attached as Exhibits 32.1 and 32.2 that accompany this Annual Report are deemed furnished and not filed with the SEC and are not to be incorporated by reference into any filing of ImmunityBio, Inc. under the Securities Act or the Exchange Act, whether made before or after the date of this Annual Report, irrespective of any general incorporation language contained in such filing.

# Indicates a management contract or compensatory plan.

\+ Some information has been redacted pursuant to Item 601of Regulation S-K. The company agrees to furnish to the SEC a copy of any redacted information upon request.

ITEM 16. FORM 10-K SUMMARY.

None.

SIGNATURES

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

IMMUNITYBIO, INC.
Registrant

Date: March 3, 2025

By: /s/ Richard Adcock
Richard Adcock
Chief Executive Officer
(Principal Executive Officer)

Date: March 3, 2025

By: /s/ David C. Sachs
David C. Sachs
Chief Financial Officer
(Principal Financial Officer)

Date: March 3, 2025

By: /s/ Regan J. Lauer
Regan J. Lauer
Chief Accounting Officer
(Principal Accounting Officer)

POWER OF ATTORNEY

Each person whose signature appears below constitutes and appoints Richard Adcock, David C. Sachs and Jason Liljestrom, and each of them, as his or her true and lawful attorney-in-fact and agent, with full power of substitution and resubstitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign any and all amendments to this Annual Report, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or any of them, or their or his substitutes, may lawfully do or cause to be done by virtue thereof.

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

Signature	Title	Date
/s/ Patrick Soon-Shiong **Patrick Soon-Shiong**	Global Chief Scientific and Medical Officer, and Executive Chairman of the Board of Directors	March 3, 2025
/s/ Richard Adcock **Richard Adcock**	Chief Executive Officer, President and Director *(Principal Executive Officer)*	March 3, 2025
/s/ David C. Sachs **David C. Sachs**	Chief Financial Officer *(Principal Financial Officer)*	March 3, 2025
/s/ Regan J. Lauer **Regan J. Lauer**	Chief Accounting Officer *(Principal Accounting Officer)*	March 3, 2025
/s/ Barry J. Simon **Barry J. Simon**	Chief Corporate Affairs Officer and Director	March 3, 2025
/s/ Michael Blaszyk **Michael D. Blaszyk**	Director	March 3, 2025
/s/ Wesley Clark **Wesley Clark**	Director	March 3, 2025
/s/ Cheryl L. Cohen **Cheryl L. Cohen**	Lead Independent Director	March 3, 2025
/s/ Linda Maxwell **Linda Maxwell**	Director	March 3, 2025
/s/ Christobel Selecky **Christobel Selecky**	Director	March 3, 2025

ImmunityBio.com

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HelpAST@equiniti.com
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Audit Firm:

Deloitte & Touche LLP