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DELTA REPORT

10-K

IOBT - IO BIOTECH, INC.

10-K - DECEMBER 31, 2023 COMPARED TO 10-K - DECEMBER 31, 2022

The following comparison report has been automatically generated

TOTAL DELTAS	3665
CHANGES	267
DELETIONS	1884
ADDITIONS	1514

REFINITIV

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, 2022 2023

OR

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

Commission File Number 001-41008

IO BIOTECH, INC.

(Exact name of Registrant as specified in its Charter)

Delaware	**87-0909276**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
Ole Maaløes Vej 3 **DK-2200 Copenhagen N** **Denmark**	**NA**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: +45 7070 2980

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 $0.001 per share	IOBT	The Nasdaq Stock Market LLC

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

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

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

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

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

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

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

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

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

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

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

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

As of June 30, 2022 June 30, 2023, the last day of the registrant's most recently completed second fiscal quarter, the aggregate market value of the Common Stock held by non-affiliates of the registrant was approximately $73.1 31.1 million.

The number of shares of Registrant's Common Stock, par value $0.001 per share, outstanding as of March 9, 2023 February 28, 2024 was 28,815,267 65,880,914.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's proxy statement relating to its 2023 2024 Annual Meeting of Stockholders have been incorporated by reference herein in response to Part III, as specifically set forth in Part III.

Table of Contents

Summary of the Material and Other Risks Associated with Our Business

Our business is subject to numerous material and other risks and uncertainties that you should be aware of in evaluating our business. These risks include, but are not limited to, the following:

- We have a limited operating history, have incurred net losses since our inception, and anticipate that we will continue to incur significant losses for the foreseeable We may never generate any revenue or become profitable or, if we achieve profitability, may not be able to sustain it.
- Our development efforts are in the early stages. All of our product candidates are in clinical development or in preclinical development. If we are unable to advan product candidates through clinical development, obtain regulatory approval and ultimately commercialize our product candidates, or experience significant delays ir so, our business will be materially harmed.
- The results of preclinical studies and early clinical trials are not always predictive of future results. Any product candidate that we advance in clinical trials, including IO103, may not achieve favorable results in later clinical trials, if any, or receive marketing approval.
- We have experienced, and may in the future experience, delays or difficulties in clinical trial site activation and the enrollment and/or retention of patients in clinica which could delay or prevent our receipt of necessary regulatory approvals.
- Our preclinical studies and clinical trials may fail to demonstrate the safety and efficacy of our product candidates, or serious adverse or unacceptable side effects r identified during the development of our product candidates, which could prevent, delay or limit the scope of regulatory approval of our product candidates, lim commercialization, increase our costs or necessitate the abandonment or limitation of the development of some of our product candidates.
- Our success and commercial opportunity largely depends on the success of our limited number of product candidates. If any of these candidates fail in clinical trials not approved for commercialization, our ability to generate revenue and achieve profitability could be impacted if we fail to develop additional product candidates.
- The We rely on third-party contract manufacturing organizations (CMOs) to manufacture of our product candidates, is complex and we which can be complex. Our may encounter difficulties in production, particularly with respect to process development or scaling-out scale-up of our manufacturing capabilities. product candida we our CMOs encounter such difficulties, our ability to provide supply of our product candidates for clinical trials or our products for patients, if approved, could be dela stopped.
- We will need to obtain substantial additional funding to complete the development and commercialization of our product candidates. If we are unable to raise this when needed, we may be forced to delay, reduce or eliminate our product development programs or other operations.
- We face substantial competition, which may result in others discovering, developing or commercializing products more quickly or marketing them more successfully th do.
- If we are unable to obtain and maintain sufficient intellectual property protection for our platform technologies and product candidates, or if the scope of the intel property protection is not sufficiently broad, our competitors could develop and commercialize products similar or identical to ours, and our ability to succe commercialize our products may be adversely affected.
- The outbreak of COVID-19, Public health emergencies, geopolitical conflicts or similar public health crises, other significant domestic and international events could l material adverse impact on our business, financial condition and results of operations, including the execution of our planned clinical trials.
- The stock proposals to revise the European Union (EU) legislation on pharmaceutical products could lead to uncertainties over the regulatory framework that applicable to medicinal products in the EU, including orphan and pediatric medicinal products.
- The price of our common stock may be volatile or may decline regardless of our operating performance and you may lose all or part of your investment.
- We are subject to a variety of privacy and data security laws, and our failure to comply with them could harm our business.

- Our internal information technology systems, or those of our third-party CROs contract research organizations (CROs) or other contractors or consultants, may fail or security breaches, loss or leakage of data, and other disruptions, which could result in a material disruption of our product candidates' development programs, comp sensitive information related to our business or prevent us from accessing critical information, potentially exposing us to liability or otherwise adversely affecti business. Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements within the meaning of the federal securities laws. All statements other than statements of historical fact contained in this Annual Report on Form 10-K, including statements regarding our future results of operations and financial position, business strategy and plans and objectives of management for future operations, are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important 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.

In some cases, you can identify forward-looking statements by terms such as "may," "should," "would," "expects," "plans," "anticipates," "could," "intends," "target," "projects," "contemplates," "believes," "estimates," "predicts," "potential" or "continue" or the negative of these terms or other similar expressions. The forward-looking statements in this Annual Report on Form 10-K are only predictions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements speak only as of the date of this Annual Report on Form 10-K and are subject to a number of risks, uncertainties and assumptions described in the section titled "Risk Factors" and elsewhere in this Annual Report on Form 10-K. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Some of the key factors that could cause actual results to differ from our expectations include:

- the timing, progress and the success of our clinical trials of IO102-IO103, IO112, IO170 and any other product candidates, including statements regarding the of initiation and completion of studies or trials and related preparatory work, the period during which the results of the trials will become available and our re and development programs;
- whether the results of our trials will be sufficient to support domestic or foreign regulatory approvals for IO102-IO103, IO112, IO170 or any other product cand we may develop;
- regulatory actions with respect to our product candidates or our competitors' products and product candidates;
- our ability to obtain, including on an expedited basis, and maintain regulatory approval of IO102-IO103, IO112, IO170 or any other product candidates w develop;
- the outcomes of our preclinical studies;
- our ability to enroll patients in our clinical trials at the pace that we project;
- our ability to establish and conduct our clinical programs on our expected timelines;
- the costs of development of any of our product candidates or clinical development programs;
- our expectation about the period of time over which our existing capital resources will be sufficient to fund our operating expenses and capital expenditures;
- the potential attributes and clinical benefits of the use of IO102-IO103, IO112, IO170 or any other product candidate, if approved; approved by the re regulatory bodies;
- our ability to successfully commercialize IO102-IO103, IO112, IO170 or any other product candidates we may identify and pursue, if approved; approved relevant regulatory bodies;
- our ability to successfully establish or maintain collaborations or strategic relationships for our product candidates;
- the rate and degree of market acceptance of IO102-IO103, IO112, IO170 or any other product candidates we may identify and pursue;

- our ability to obtain orphan drug designation, Breakthrough Therapy Designation (BTD), accelerated or other approval for any of our product candidates w identify;
- our expectations regarding government and third-party payor coverage and reimbursement;

- our ability to manufacture, including through contract manufacturing organizations (CMOs), CMOs, IO102-IO103, IO112, IO170 or any other product candi conformity with the Food and Drug Administration's (FDA's) requirements and the requirements of other applicable regulatory authorities;
- our ability to successfully build a sales force and commercial infrastructure;
- our ability to compete with companies currently producing or engaged in the clinical development of treatments for the disease indications that we pursu treatment modalities that we develop;
- our reliance on third parties to conduct our clinical trials;
- our reliance on third-party CMOs to manufacture and supply our product candidates for us;
- our ability to retain and recruit key personnel;
- our ability to obtain and maintain intellectual property protection for IO102-IO103, IO112, IO170 or any other product candidates we may identify and pursue;
- our estimates of our expenses, ongoing losses, future revenue, capital requirements and our needs for or ability to obtain additional financing;
- our expectations regarding the time during which we will be an emerging growth company (EGC) under the Jumpstart Our Business Startups Act (JOBS Act);
- our financial performance;
- the effect of the COVID-19 pandemic, including mitigation efforts and economic effects, and other significant public health emergencies or geopolitical events of the foregoing or any other aspects of our business operations;
- the impact of laws and regulations, including legislative developments; and
- developments and projections relating to our competitors or our industry.

These statements relate to future events or to future financial performance and 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 these forward-looking statements. Factors that may cause actual results to differ materially from current expectations include, among other things, those set forth in Part II, Item 1A - “Risk Factors” below and those described elsewhere in this Annual Report on Form 10-K. Any forward-looking statement in this Annual Report on Form 10-K reflects our current view with respect to future events and is subject to these and other risks, uncertainties, and assumptions relating to our operations, results of operations, industry, and future growth. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

This Annual Report on Form 10-K also contains estimates, projections, and other information concerning our industry, our business, and the markets for certain drugs, including data regarding the estimated size of those markets, their projected growth rates, and the incidence of certain medical conditions. Information that is based on estimates, forecasts, projections, 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 these industry, business, market, and other data from reports, research surveys, studies, and similar data prepared by third parties, industry, medical and general publications, government data, and similar sources. In some cases, we do not expressly refer to the sources from which these data are derived.

Except where the context otherwise requires, in this Annual Report on Form 10-K, “we,” “us,” “our,” “IO Biotech,” and “the Company” refer to IO Biotech, Inc. and, where appropriate, its consolidated subsidiaries.

Trademarks

We have applied for various trademarks that we use in connection with the operation of our business. This Annual Report on Form 10-K includes trademarks, service marks, and trade names owned by us or other companies. All trademarks, service marks, and trade names included in this Annual Report on Form 10-K are the property of their respective owners. Solely for convenience, the trademarks and trade names in this report may be referred to without the ® and ™ symbols, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto.

PART I

Item 1. Business.

Overview

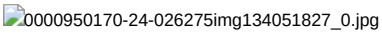
We are a clinical-stage biopharmaceutical company developing novel, immune-modulating therapeutic cancer vaccines based on our T-win technology T-win® platform. Our T-win product candidates are designed to induce kill both tumor cells and immune-suppressive cells in the immune system to simultaneously tumor microenvironment (TME) by stimulating the activation and expansion of T cells against IDO+ and/or PD-L1+ target positive cells, resulting in the modulation of the TME, creating a more pro-inflammatory environment, and disrupt multiple pathways that regulate tumor-induced immunosuppression. the potentiation of anti-tumor activity by unleashing the tumor killing by effector T cells. We believe this represents could represent a paradigm shift in the management of cancer and that our product candidates have the potential to become cornerstones advance the oncology treatment paradigm, amplifying treatment effects across the spectrum of the treatment regimens of multiple solid tumors. melanoma and other tumor types. Our lead product therapeutic cancer vaccine candidate, IO102-IO103, is designed to target the immunosuppressive mechanisms mediated by key immunosuppressive proteins such as Indoleamine indoleamine 2,3-dioxygenase (IDO) and programmed death ligand 1 (PD-L1). In a single-arm Phase 1/2 clinical trial of 30 patients with metastatic melanoma, with the primary objective of investigating safety and tolerability, the secondary objective of investigating immunogenicity, and the tertiary objective of investigating clinical efficacy, IO102-IO103 in combination with nivolumab, an anti-programmed cell death 1 (PD-1) checkpoint inhibitor, demonstrated proof of concept by increasing the overall response rate (ORR) of what is reported with an ability to induce anti-PD-1 antibody alone. The combination induced meaningful tumor regression and establish achieved rapid, deep and durable antitumor response while achieving responses with a manageable favorable tolerability profile for patients. without adding systemic toxicity to what is seen with an anti-PD-1 monotherapy in this patient population. Safety was the primary endpoint of this trial, immune response was the secondary endpoint and clinical efficacy was the tertiary endpoint. The clinical efficacy endpoints in this trial included objective response (OR), progression free survival (PFS) and overall survival (OS). In this trial, we observed a confirmed overall response rate (ORR) ORR of 73% and as per RECIST 1.1, a complete response rate (CRR) of 50%. and 25.5 months of PFS. Based on the these results, from this trial, IO102-IO103, in combination with pembrolizumab, was granted BTD by the FDA for treatment of unresectable/metastatic melanoma.melanoma and we initiated a global Phase 3 trial.

We enrolled the first patient in a potentially registrational Phase 3 trial for IO102-IO103 in combination with pembrolizumab as a potential first-line treatment in advanced melanoma, the IOB-013/KN-D18 trial, in May of 2022. We have made significant progress with randomized 225 patients in June 2023 and fully enrolled the activation trial in November 2023. On June 14, 2023, we announced that we amended the protocol and increased the number of clinical sites participating patients to be enrolled in the Phase 3 IOB-013/KN-D18 trial ending February 2023 with nearly 100 active sites in the trial, compared to 55 at the end of October 2022. The IOB-013/KN-D18 trial has a target enrollment of from original 300 patients and is designed with an interim analysis of ORR one year after 75% of to revised 380 patients, have been randomized and a final analysis of which could potentially accelerate the time to reach the primary endpoint of PFS, for the full trial population. We expect to enroll 75% of patients which is an event-based driven analysis and will be assessed when 226 events (progression or death) are registered in the trial. The primary endpoint is powered at 89% to detect a hazard ratio of 0.65. The Phase 3 trial by mid-2023 and protocol has a planned interim analysis of ORR to complete recruitment by be conducted 12 months after 225 patients have been randomized; if the end investigational arm demonstrates a highly statistically significant improvement in ORR compared to the control arm, with a p-value<0.005, then the interim analysis could allow for potential submission of 2023. a Biologics License Application (BLA) for accelerated approval in the United States. When we designed the interim analysis, we assumed that patients treated with IO102-IO103 in combination with pembrolizumab would show an ~18-point improvement in ORR compared to the patients treated with pembrolizumab alone. The trial design and discussions with FDA are aimed at potentially pursuing accelerated approval, if the trial data are favorable, based on the interim analysis of ORR, supported by other data. If the data are supportive, we also plan to file a Marketing Authorization Application (MAA) with the European Medicines Agency (EMA) based on the primary endpoint of PFS.
PFS after the data are available, which is expected to occur in the second half of 2025.

Our T-win platform is a novel approach to cancer vaccines designed to activate pre-existing T cells to target immunosuppressive mechanisms. Our T-win product candidates are designed to employ a dual mechanism of action: (1) direct killing of immunosuppressive cells, including both tumor cells and genetically stable cells in the tumor microenvironment (TME), TME, that express IDO and and/or PD-L1 (in the case of IO102-IO103), Arginase 1 (in the case of IO112) or TGFβ1 (in the case of IO170), and (2) modulation of the TME into a more pro-inflammatory, anti-tumor environment. Our T-win technology platform is built upon our team's deep understanding of both the TME and a tumor's ability to evade surveillance and destruction by the immune system. Our approach is in contrast to previous methods that have sought to either block singular immunosuppressive pathways or to direct the immune system against specific identified antigens expressed by tumor cells.

We are developing a pipeline of product candidates that leverage our T-win technology platform to address targets within the TME. In addition to melanoma, we plan to evaluate are currently evaluating IO102-IO103 in multiple solid tumor indications to potentially expand

the market opportunity for IO102-IO103. We are also focusing on additional targets that play key roles in immunosuppression and that are expressed in a broad range of solid tumors. Our current pipeline of product candidates is and expected upcoming milestones are summarized in the table tables below.



(*) In combination with pembrolizumab

(2) NSCLC = non-small cell lung cancer, SCCHN = squamous cell carcinoma of the head and neck UBC = urothelial bladder cancer

Our lead product candidate, IO102-IO103, combines our two fully-owned, novel immune-modulating vaccines, IO102 and IO103, which are designed to target IDO+ and PD-L1+ target cells, respectively. IDO and PD-L1 are often dysregulated and over-expressed in a wide range of solid tumors, and result in the inhibition of the body's natural pro-inflammatory anti-tumor response within the TME. IO102-IO103 is designed to employ our novel dual mechanism of action approach. This is in contrast to previous approaches which have sought to block singular immunosuppressive pathways or to direct the immune system against specific identified antigens expressed by tumor cells. By combining IO102 and IO103 in a single treatment regimen, we also aim to provide a synergistic therapeutic effect on tumors.

On December 14, 2020, the FDA granted us BTD for the IO102-IO103 cancer vaccine in combination with pembrolizumab for the treatment of patients with unresectable or metastatic melanoma based on data from the Phase 1/2 clinical trial, MM1636. A BTD enables us to solicit more frequent and intensive guidance from the FDA as to how to conduct an efficient development program for IO102-IO103. The MM1636 trial was an investigator-initiated, single-arm Phase 1/2 trial of 30 anti PD-1/PD-L1 naïve patients with metastatic melanoma receiving IO102-IO103 and nivolumab, an anti-PD-1 monoclonal antibody. In this trial, investigators initially observed an ORR of 80% (24 out of 30 patients); however, two of 24 patients in which a response was observed progressed before subsequent radiological confirmation, which resulted in a and confirmed best ORR of 73%. In addition, based on RECIST 1.1. 50% of patients achieved a complete response (CR), or complete elimination of their tumors based on RECIST 1.1 definitions. tumors. Overall tolerability of the combination was favorable, with no significant added systemic toxicity from what has been reported with nivolumab alone. While a total of five patients (17%) experienced a treatment-related high-grade adverse event (grade 3-5), based on the and 17% discontinuation rate of discontinued treatment with both nivolumab and IO102-IO103, data from this trial suggests a manageable tolerability profile for patients. In addition, we have observed treatment-induced infiltration of CD3/CD8 CD3+/CD8+ T cells into the tumor site in responding patients and detected IO102+ IO102 and/or IO103-specific T cells in tumors after treatment in correlative biomarker data where this was analyzed. Consistent with the earlier reported data, with an additional 15 months of patient follow-up, results from a new the January 5, 2023 data cut as published in the May 2023 Journal for the MM1636 Phase 1/2 ImmunoTherapy of Cancer from this study of IO102-IO103 in combination with nivolumab for metastatic melanoma continue to be encouraging. As of that data cut-off date, 30 PD-1 naïve patients were enrolled with a minimum follow-up time of time of 49.8 months. Median OS was not reached, median PFS was 25.5 months, and 50% of patients (15/30) achieved a CR, or complete disappearance of their tumors, and the ORR was 80% (73% confirmed ORR per RECIST 1.1). Patients who were anti-PD-1 antibody refractory therapy resistant and enrolled in cohort B in this study had no response to therapy, which we believe shows that our vaccine works best in front-line metastatic melanoma patients, as we expected in this setting.

We are currently recruiting for In November 2023, we fully enrolled a Phase 3 potentially registrational trial for IO102-IO103, the IOB-013/KN-D18 trial, in combination with pembrolizumab in anti PD-1/PD-L1 treatment naive naïve patients with unresectable or metastatic melanoma. While the MM1636 trial investigated IO102-IO103 in combination with nivolumab, we have made the commercial decision to investigate IO102-IO103 in combination with pembrolizumab in the Phase 3 trial. Nivolumab and pembrolizumab are both IgG4 immunoglobulan G4 (IgG4) subclass antibodies that target the PD-1 receptor. In a comparative data analysis

by Moser (Annals of Oncology 2020), researchers found no difference between the effectiveness of frontline pembrolizumab and nivolumab in patients with advanced melanoma. The Phase 3 trial also includes a concurrent evaluation of the initial participants to allow for an assessment of safety (a safety run-in) for the combination of IO102-IO103 and pembrolizumab. The pembrolizumab for this trial is being supplied by Merck pursuant to a Clinical Trial Collaboration and Supply Agreement that we entered into in September 2021. The independent data monitoring committee (IDMC) for the IOB-013/KN-D18 trial convened its first third meeting in December 2022 to review initial safety data from September 2023 and the trial and IDMC recommended that the trial continue without any modifications.

We are also developing investigating the IO102-IO103 for cancer vaccine in several other solid tumor indications. We are conducting a Phase 2 basket trial, the IOB-022 trial (KN-D38), which will enable us to investigate multiple first-line solid tumor indications in anti PD-1/PD-L1 treatment naïve patients with for metastatic disease. This basket trial is designed to investigate the safety and efficacy of IO102-IO103 in combination with pembrolizumab in patients with metastatic non-small cell lung cancer (NSCLC), adenocarcinoma histology, with PD-L1 TPS ☐ ≥ 50%, (cohort A) or recurrent and/or metastatic squamous cell carcinoma of the head and neck (SCCHN) with CPS ☐ ≥ 20 and urothelial bladder carcinoma (UBC) with CPS ☐ 10. (cohort B). We initiated the IOB-022 trial in April 2022. We announced encouraging initial 2022 and as of August 21, 2023, 42 patients were enrolled (28 in cohort A and 14 in cohort B). Consistent with the earlier reported data, preliminary results from the first IOB-022/KN-D38 Phase 1/2 study of IO102-IO103 in combination with pembrolizumab in metastatic NSCLC or recurrent and/or metastatic SCCHN continue to be encouraging as presented at the European Society for Medical Oncology (ESMO) conference held in October 2023. Of the 28 patients enrolled in the study in January 2023. Of the 10 patients enrolled, 9 cohort A, 18 were efficacy evaluable per protocol having received at least one two full cycle cycles of treatment. Among the 9 18 evaluable patients, 4 10 patients had a partial response as their best overall response while 4 5 had stable disease; one patient disease and 3 patients had progressive disease. Of the 14 patients enrolled in cohort B, 6 were efficacy evaluable per protocol having received at least two full cycles of treatment. Among the 6 evaluable patients, 3 patients had a partial response as their best overall response while 3 patients had progressive disease. The safety profile observed to date in this study is consistent with prior clinical experience with IO102-IO103. We expect to report additional data from this study in 2023.

In addition to first-line cancer indications, we also plan have initiated a trial to investigate IO102-IO103 when in combination with pembrolizumab in a perioperative setting and used before or after curatively intended surgery as a neo-adjuvant/adjuvant therapy. As In April 2023, the FDA cleared the Company's Investigational New Drug (IND) application for the evaluation of IO102-IO103 in combination with our targeted first-line cancer indications, we plan to conduct a Phase 2 basket trial, pembrolizumab, given before (neo-adjuvant) and after (adjuvant) surgery in patients with resectable melanoma and squamous cell carcinoma of the head and neck, the IOB-032 trial which (PN-E40). We anticipate that the study will enable us to investigate multiple solid tumor indications in anti PD-1/PD-L1 naïve settings focused initially on enroll approximately 15 patients with melanoma and SCCHN. 15 patients with SCCHN, each of whom will be a candidate for surgical resection with curative intent and will not have experienced prior systemic therapy for the tumor under study. We expect that patients entering the study will begin neoadjuvant treatment 4-9 weeks prior to surgery for their respective tumor indication. During the 4-9 week neoadjuvant period, patients will receive IO102-IO103 in combination with pembrolizumab every 3 weeks (Q3W) for 3 cycles (melanoma) or 2-3 cycles (SCCHN). After patients recover from surgery, they will receive adjuvant treatment with IO102-IO103 in combination with pembrolizumab Q3W for up to 15 cycles. The primary endpoint will be major pathologic response (MPR) in the resected tumor tissue after neoadjuvant treatment; secondary endpoints will be pathological CR and ORR; and other endpoints will be disease-free survival (DFS), event-free survival (EFS), and safety. We announced in a press release issued on December 21, 2023 that the first patient in the IOB-032 trial was enrolled and dosed. In addition, we also filed a protocol amendment with the FDA in December 2023 to initiate this trial enrollment of 30 new patients with resectable melanoma in a randomized cohort C study in the IOB-032 trial. Patients in cohort C will be randomized 1:1 to receive the neoadjuvant treatment of either IO102-IO103 in combination with pembrolizumab or pembrolizumab alone, and will continue with the same regimen in the post-surgery phase. We are currently awaiting response from the FDA and, if the amendment is approved, we project that we will commence with the amended protocol in the second half quarter of 2023.
2024.

Our development of the IO102-IO103 combination is based on our prior separate development of IO102 and IO103. IO102 is our fully-owned fully owned novel product candidate containing a single IDO-derived peptide sequence designed to engage and activate IDO-specific human T cells. IDO small molecule inhibitors have shown clinical potential in combination with PD-1 antibodies in early clinical trials, but have not been able to demonstrate the same level of efficacy in later-stage clinical trials. Our Phase 1 non-randomized trial of IO101, our first-generation IDO therapy, in NSCLC resulted in proof of concept for our approach, with 47% of patients displaying clinical benefit and an OS of 26 months in the treatment arm compared to 8 months in the group receiving standard of care. There were no grade 3 or higher adverse events (AEs). We have completed testing of IO102 in a randomized Phase 1/2 trial in combination with pembrolizumab standard-of-care in first-line treatment of patients with metastatic NSCLC. IO103 is our fully-owned, novel product candidate containing a single PD-L1-derived peptide designed to engage and activate PD-L1 specific human T cells. Continued clinical development of IO102 and IO103 will be focused on their use in our dual- and multi-antigen approaches.

IO112 is our fully-owned, fully owned, novel product candidate containing a single Arginase 1-derived peptide designed to engage and activate Arginase 1-specific human T cells. IO112 is designed to target T cells that recognize epitopes derived from Arginase 1, which is an immunoregulatory enzyme highly expressed in difficult-to-treat tumors associated with high levels of myeloid-derived suppressor cells (MDSCs) including colorectal, breast, prostate and pancreatic and ovarian cancers. Arginase overexpression is a well-documented tumor escape mechanism. IO112 is currently being was tested in a single arm first-in-human Phase 1 trial in patients with arginase-positive Arginase-positive solid tumors conducted in an investigator-initiated trial at the University of Copenhagen. We plan to be ready to file an IND continue IND-enabling activities for IO112 in 2023.2024 and expect to initiate an IND filing in 2025.

In addition to IO102, IO103 and IO112, we are evaluating additional product candidates that we believe have potential for use in solid tumors. All our compounds in preclinical development are designed to target well-documented immunosuppressive molecules that are known to be overexpressed in the TME across a wide range of tumors. These targets provide additional opportunities across multiple cancer indications.

Targeting TGFB1 We believe that targeting transforming growth factor beta 1 (TGFβ1) expressing cells in the TME via a vaccine approach presents a novel and attractive way to modulate

the pathway and drive therapeutic benefit in the cancer setting. We are developing and characterizing TGFB1-selective TGFβ1-selective peptide vaccines capable of inducing strong immune responses. Preliminary evidence in mouse models showed that treatment with a TGFB1 TGFβ1 vaccine drives
CD4+ T cell infiltration in the TME and might promote in vivo targeted cell killing. Further We are currently conducting further experimental work to elucidate the cellular and molecular mechanisms of a TGFB1 TGFβ1 vaccine is ongoing to support further development of a TGFB1 TGFβ1 vaccine (IO170) to modulate the TME for therapeutic benefit in a wide range of cancer indications.

We were established plan to continue pre-clinical studies for IO170 in December 2014 as a spin-off of the National Center for Cancer Immune Therapy at Herlev University Hospital in Denmark. We have assembled a seasoned management team and Board with extensive experience in developing novel oncology therapies, including advancing product candidates from preclinical research through to clinical development and ultimately to regulatory approval. Our team is led by our founder, President and Chief Executive Officer, Mai-Britt Zocca, Ph.D., who has close to 20 years of experience as a biotech executive. Amy Sullivan, our Chief Financial Officer, joined us in October 2022 and brings 30 years of public company industry experience to IO Biotech. Eva Ehrnrooth, MD, Ph.D., our Chief Medical Officer, is a clinical oncologist and has more than 20 years of experience in oncology and drug development. Mads Hald Andersen, Ph.D., our scientific founder and advisor, is a Professor and director at the National Center for Cancer Immune Therapy, Herlev University Hospital and an internationally recognized immunology researcher. Muhammad Al-Hajj, Ph.D., our Chief Scientific Officer, is a well-respected scientific leader with a proven-track record in the field of immuno-oncology and expertise in translational medicine and biomarker discovery. Our Board has deep expertise in the fields of immuno-oncology, business and finance.
2024.

Our Strategy

To achieve our goals, we aim to leverage our T-win T-win® platform to transform cancer treatments by creating a broad portfolio of cancer vaccines focused on targets within the TME.

The key elements of our strategy are to:

- *Advance our lead product candidate, IO102-IO103, toward approval in combination with anti-PD-1 therapy in first-line treatment of advanced melanoma.* We were granted BTD by the FDA based on a confirmed ORR of 73% as per RECIST and CRR of 47% 50% in MM1636, the Phase 1/2 clinical trial of IO102-IO103 in combination with nivolumab in first-line treatment of patients with melanoma. We enrolled the first patient in the IOB-013/KN-D18 trial in May of 2022. We have made significant progress with 2022, randomized 225 patients as of June 2023, at which time we also increased the activation total number of clinical sites participating patients to be enrolled to 380 patients, and subsequently fully enrolled and randomized the trial in the November 2023. The Phase 3 IOB-013/KN-D18 trial ending February 2023 with nearly 100 active sites in the trial, compared to 55 at the end of October 2022. The IOB-013/KN-D18 trial protocol has a target enrollment of 300 patients and is designed with an planned interim analysis of ORR one year 12 months after 75% of 225 patients have been randomized and a final analysis of the primary endpoint of PFS for the full trial population. We expect to enroll 75% of patients in the trial by mid-2023 and to complete recruitment by the end of 2023. randomized. The trial design and discussions with the FDA are aimed at potentially pursuing accelerated approval if in the trial data are favorable, based on event the interim analysis of investigational arm demonstrates a highly statistically significant improvement in ORR compared to the control arm, with a p-value<0.005, as further supported by other data. If In addition, if the data are is supportive, we also plan to file an MAA with the EMA based on the primary endpoint of PFS; PFS, once data related to this endpoint is available, which we expect in the second half of 2025;

- *Broaden clinical development of IO102-IO103 into other solid tumor settings through basket trials in the first line metastatic and neo-adjuvant / adjuvant treatment settings.* We are executing a Phase 2 basket trial, the IOB-022 trial, of IO102-IO103 in combination with pembrolizumab in the first line solid tumor setting. This basket trial enrolls PD-1/PD-L1 treatment naïve patients with metastatic disease, including NSCLC (cohort A) and SCCHN and UBC. (cohort B). We enrolled the first patient in our Phase 2 basket trial in solid tumors in 2022 and released encouraging preliminary initial data from the evaluable 42 patients enrolled in January the IOB-022 study in August 2023. Of the 10 28 patients enrolled 9 in cohort A, 18 were efficacy evaluable per protocol having received at least one two full cycle cycles of treatment. Among the 9 18 evaluable patients, 4 10 patients had a partial response as their best overall response while 4 5 had stable disease;

one patient disease and 3 patients had progressive disease. Of the 14 patients enrolled in cohort B, 6 were efficacy evaluable per protocol having received at least two full cycles of treatment. Among the 6 evaluable patients, 3 patients had a partial response as their best overall response while 3 patients had progressive disease. The safety profile observed to date in this study is consistent with prior clinical experience with IO102-IO103. IO102-IO103 with no added systemic toxicity. We expect to report additional data from this study in 2023. We also plan to initiate a 2024. Additionally, in April 2023, the FDA cleared the Company's IND for the evaluation of IO102-IO103 in the neo-adjuvant/adjuvant treatment of solid tumors in the IOB-032 trial. As with our targeted first-line cancer indications, we are conducting this Phase 2 basket trial IOB-032, of to investigate IO102-IO103 in combination with anti-PD-1 antibody therapy pembrolizumab in the neo-adjuvant / adjuvant treatment setting. multiple solid tumor indications in anti PD-1/PD-L1 naïve settings focused initially on melanoma and SCCHN. In this trial, combination therapy will be used before and after curatively intended surgery. This basket trial will enable us to investigate multiple solid tumor indications in anti PD-1/ PD-L1 naive patients, and will focus initially on melanoma and SCCHN. surgical resection with curative intent. We expect to initiate report initial data from this trial study in the second half of 2023 and receive data in 2024. 2025. These two basket trials build on the data that we have generated from prior trials of our single epitope product candidates, IO102 and IO103, including the anti-tumor activity that we have observed with the use of our first-generation IDO compound in NSCLC;

- *Leverage our T-win technology platform to design and advance a portfolio of novel immune-modulating cancer vaccine product candidates, including IO112 and additional future product candidates.* Since inception, our T-win platform has allowed us to rapidly identify and develop multiple pipeline candidates. Our next product candidate, IO112, targets Arginase 1, which is over-expressed in solid tumors where MDSCs are known to play key roles in immune resistance. IO112 is currently being tested in a single arm first-in-human Phase 1 trial in patients with arginase-positive Arginase-positive solid tumors conducted in an investigator-initiated trial at the University of

Copenhagen. We plan to be ready to file an IND continue IND-enabling activities for IO112 in 2023. 2024 and expect to initiate an IND filing in 2025. We are contin evaluate other targets within the TME, including TGFB, TGFβ1 and intend to leverage our T-win T-win® platform to bring additional product candidates into the clin time which could be used alone or in combination with other candidates; candidates. We believe that targeting TGFβ1 expressing cells in the TME via a vaccine ap presents a novel and attractive way to modulate the pathway and drive therapeutic benefit in cancer setting. We are currently developing and characterizing T selective peptide vaccines capable of inducing strong immune responses. We plan to continue pre-clinical studies of a TGFβ1 vaccine in 2024;

- *Strengthen our position in the immunotherapy field through the continuous innovation and expansion of our T-win platform.* We have extensive knowledge about the characterization of immunosuppressive mechanisms in the TME and pharmacology. We plan to continue investing in our platform in order to stay at the forefront of developments in the immunotherapy space. Our platform is supported by a strong patent portfolio consisting of 17 different families, filed in all major markets with a long exclusivity periods. markets. We plan to continue investing in intellectual property to support our platform and product candidates;
- *Maximize the value of our product candidates and pipeline by selectively entering into strategic collaborations*. We hold worldwide development and commercial rights to our pipeline of compounds, and we intend to commercialize our product candidates, if approved, in key geographies. We have entered, and may enter in the future, into collaborations that grant us access to certain compounds owned by third parties to enable therapeutic combinations that could enhance the clinical and commercial potential of our four product candidates. For example, we have entered into a non-exclusive, clinical supply agreement with MSD International GmbH (MSDIG)/Merck, to evaluate IO102-IO103 in combination with pembrolizumab plus chemotherapy and as a neo-adjuvant/adjuvant therapy; and
- *Build a leading immuno-oncology immune-modulating therapeutic cancer vaccine company while maintaining a strong culture of innovation, valuing diversity and putting patients at the center of everything we do.* We will continue to apply our deep understanding of the TME to the discovery and development of novel immune-modulating therapeutic cancer vaccines that have the potential to provide breakthroughs for cancer patients who are currently underserved by available therapies. We place a high value on the diversity of our team – including gender, background and expertise – to foster this culture of innovation.

Our Approach to Therapeutic Cancer Vaccines

Our product candidates are designed to induce the immune system to simultaneously target and disrupt multiple pathways that regulate tumor-induced immunosuppression. We believe this represents a paradigm shift in the management of cancer and that our product candidates have the potential to become cornerstones of the treatment regimens of multiple solid tumors. Our T-win technology platform is built upon our team's deep understanding of both the TME and a tumor's ability to evade surveillance and destruction by the immune system.

The Role of the Immune System in Fighting Cancer

The Immune System

The immune system is a dynamic and self-regulating network of cells and molecules that cooperate to help the body fight disease. It is able to detect pathogens and can distinguish abnormal cells, such as tumor cells, from healthy tissue. The immune system has evolved to detect such dangers to the body through the detection of molecules or molecular structures called antigens. When exposed to pathogens or abnormal cells, the immune system responds by recognition of antigens and becomes activated to defend against them. The first line of biological defense is a general, rapid response by the innate immune system which is essential for immediate recognition and attack of pathogens as

well as tumor cells. This innate response then activates and triggers a more targeted response by the adaptive immune system. Through such adaptive immune responses, the body can develop long-term immunity, or immunologic memory, to specific pathogens and other threats. Immunologic memory is established through generation of specific B cells and T cells, equipping the body to recognize, counteract and neutralize pathogens and other threats, such as cancer cells.

The intricate system of how immune cells interact and propagate a signal to elicit an immune response in cancer is known as tumor immune regulation. Successful antitumor immunity requires optimal interactions between immune and non-immune constituents of the TME. The immune system comprises is comprised of both activating and suppressing functions built up by a myriad of different cell types. These various immune cells function to activate or suppress immune activity. We have described some of the key cellular factors contributing to anti-tumor immunity below and have classified them as immune activators or immune suppressors. However, many of these cells cell types can differentiate and acquire distinct functions in response to changing circumstances, known as cellular plasticity, which allows cells to switch from being immune activating to immune suppressing, or the reverse, based on certain immune triggers.

The Key Immune Activators and Suppressors in Anti-tumor Responses

Cell types	Immune Activators	Immune Suppressors
Antigen Presenting Cells (APCs) A group of immune cell types that mediate cellular immune responses by processing and presenting antigens to lymphocytes.	***Macrophages and Dendritic cells*** *Both termed professional APCs, because of their ability to initiate a T cell response to novel antigens.*	**Tumor-associated macrophages (TAMs), tolerogenic DCs dendritic cells (DCs) and myeloid-derived suppressor cells (MDSCs)** These are part of the heterogeneous population of APCs that inhibits T cell functions.
T cells / T lymphocytes Specialized white blood cells that recognize and destroy infected or unhealthy cells, such as tumor cells.	***Effector T cells*** *Effector T cells consists of two main groups:* ***CD4+ T Cells*** *Also known as helper T cells, CD4+ T cells produce cytokines and help maximize the expansion of the CD8+ T cell population in a primary immune response and facilitate the generation of specific memory CD8+ T cells; and* ***CD8+ T Cells*** *Also known as cytotoxic T cells, CD8+ T cells kill tumor cells, as well as infected and damaged cells. They express T cell receptors (TCRs), which recognize and bind to specific antigens expressed by cancer cells and infected cells which are presented on the surface of the cells.*	**Regulatory T cells (Tregs)** Tregs suppress activation, proliferation and cytokine production of CD4+ and CD8+ T cells and APCs.

The immune system has the capacity to detect tumor cells and employ a variety of biological mechanisms, or immune effector functions, to specifically target and destroy these cells. However, tumors are adept at undermining the normal immune system functions that allow cancer cells to evade such detection and destruction.

The Tumor Microenvironment

Tumors can generate signals that promote tumor growth and suppress immune system functions. The TME is an immunosuppressive environment that surrounds a tumor and includes blood vessels, immune cells, and signaling molecules. A significant portion of the immune reaction against tumors occurs within the TME. There is constant interplay between the TME and the tumor itself, as signals from the tumor can facilitate immunosuppression and tumor growth. In recent years, growing understanding of this interplay has led to the successful development of therapies that modulate specific immunosuppressive mechanisms within the TME to activate the immune system against cancer cells.

Within the TME, several molecules have been identified that play critical roles in regulating immune functions. These include:

- **PD-1/PD-L1**: PD-1 and its ligand, PD-L1, are critical regulators of the immune system, known as immune checkpoints. The interactions between PD-1 with its ligand PD-L1 inhibit T cell effector functions against tumor cells. Tumor cells can upregulate PD-L1 to evade the attack of the immune system and PD-L1

expression is correlated with increased tumor aggressiveness and poor patient prognosis. PD-L1 expression has been reported for both hematological cancer and solid tumors;

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- **IDO**: IDO is a metabolic enzyme that regulates immune function through depletion of tryptophan, which is essential for T cell effector function, as well as production of immunosuppressive metabolites such as kynurenine. Such depletion of tryptophan and production of kynurenine is also known as canonical immune suppression. IDO also suppresses immunity through non-enzymic effects, known as non-canonical immunosuppression. IDO has

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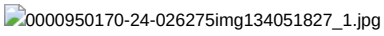
been demonstrated to be a critical cellular factor contributing to the suppression of anti-cancer immunity. IDO is expressed in many solid tumors and hematological malignancies and its activity has been shown to correlate with a poor prognosis prognoses and reduced rates of survival;

- **Arginase**: Arginase 1 (arginase) is an enzyme that contributes to immune regulation by catabolizing and limiting the availability of arginine, which is essential for immune effector cell survival and growth. Arginase overproduction by immunosuppressive cells such as MDSCs is a well-documented tumor escape mechanism. Arginase is highly expressed in difficult-to-treat cancers, including colorectal, breast, prostate, pancreatic and ovarian cancers, and it is associated with high levels of MDSCs; and
- **Transforming growth factor-ß TGFIβ1**: Transforming growth factor-ß TGFβ1 is one of the key molecules that contribute to immunosuppression and it is produced in large amounts in the TME by not only by cancer cells but also by suppressive and regulatory cells. Targeting TGFB1 We believe targeting TGFβ1 expressing cells in the TME via a vaccine approach presents a novel and attractive way to modulate
the pathway and drive therapeutic benefit in cancer setting. We are developing and characterizing TGFB1-selective peptide vaccines capable of inducing strong immune responses. Preliminary evidence in mouse models showed that treatment with a TGFB1 TGFβ1 vaccine drives CD4+ T cell infiltration in the TME and might promote in vivo targeted cell killing. Further experimental work to elucidate the cellular and molecular mechanisms of a TGFB1 vaccine is ongoing to support further development of a TGFB1 vaccine.

These immune markers are often dysregulated and over-expressed in a wide range of cancers. The figure below shows the role of these molecules in immunosuppression within the TME:

Figure 1: Selected Drivers of Immunosuppression in the TME.TME



Engaging the Immune System to Fight Cancer

In recent years, rapidly growing understanding of the interaction between cancer and the immune system, known as immuno-oncology, has led to the development of a number of therapeutic approaches that aim to counter the tumor-driven immunosuppression in the TME, to allow the immune system to fight cancer. These approaches include:

- **Checkpoint Inhibitors**: Checkpoint inhibitors include PD-1, PD-L1 Antibodies antibodies and CTLA-4 cytotoxic T-lymphocyte associated protein 4 (CTLA-4), among others. PD-1 and PD-L1 antibodies block the immunoregulatory functions of PD-1 and PD-L1, respectively, allowing T cell-mediated immune responses against tumor cells. PD-1 and PD-L1 antibody therapies have shown significant clinical efficacy resulting in broad commercial success. However, while such therapies are highly effective in certain subsets of patients with specific types of tumor, there are a significant number of cancer patients for whom these therapies are not effective; effective.

11 14

- **IDO Inhibitors**: IDO inhibitors aim to alleviate the immunosuppressive effects of the IDO protein by blocking one of its well-established biological functions, functions: its enzymatic activity responsible for converting tryptophan (a desirable T cell metabolite) into kynurenine (a non-desirable T cell metabolite contributing to a hostile tumor microenvironment). This is often referred to as the canonical immune suppressive function of IDO. However, there is also evidence demonstrating that the protein induces immune suppression of T-cells T cells via a mechanism independent of tryptophan conversion, often referred to as the non-canonical immune suppressive functions function of the IDO protein. IDO. Hence, blocking the immune suppressive activity of IDO will likely require blocking all its

related functions. IDO inhibitors have shown clinical potential in combination with anti-PD1 antibodies in early-stage trials but have not been able to demonstrate the same level of efficacy in late-stage clinical trials.

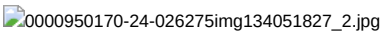
- **Peptide immunotherapies**: These therapies are based on peptides which represent tumor antigens, pieces of a key protein, or surface markers on the cancer cell, and whose presentation to the adaptive immune system leads to a specific immunological response directed at that their target. Their aim is to direct immune system effector functions, including CD8+CD8+ T cells, against antigens expressed on tumor cells. Although previous peptide immunotherapies have demonstrated attractive safety and tolerability profiles, they have only demonstrated modest clinical efficacy to date, likely reflecting (i) the ability of tumors to escape immune recognition by loss of antigens and (ii) the ability of tumors to orchestrate an immunosuppressive microenvironment. Collectively, these abilities are referred to as tumor immune escape.

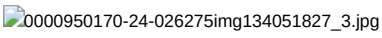
These immuno-oncology approaches have typically sought to block a single immunosuppressive pathways pathway employed by tumors or to direct the immune system against antigens or neoantigens expressed by tumors cells. We believe that, by directing the immune system against both tumor cells and other healthy cells within the TME that express immunosuppressive molecules such as PD-1 or IDO, we have the potential to drive significant benefits for patients by transforming the immune balance within the TME.

Our Approach: Targeting The TME With Our T-win® Technology Platform

Our T-win vaccine platform is a novel approach to cancer vaccines designed to activate naturally occurring pre-existing T cells to target immunosuppressive mechanisms. Our T-win product candidates are designed to employ a dual mechanism of action: (1) direct killing of immunosuppressive cells, including both tumor cells and genetically stable cells in the TME, that express key immunosuppressive proteins such as IDO and PD-L1 and (2) modulation of the TME into a more pro-inflammatory, anti-tumor environment. This is in contrast to previous methods that have sought either to only block singular immunosuppressive pathways or to direct the immune system against specific identified antigens expressed only by tumor cells. We believe that our dual mechanism approach has the potential to induce tumor regression, establishing establish lasting and durable antitumor response, and to achieve manageable tolerability for patients.

Our T-win platform is based on the our discovery of naturally occurring, pro-inflammatory T cells which can be used against immunosuppressive mechanisms mediated by key immunosuppressive proteins, such as IDO and PD-L1, that are present in the periphery and among tumor-infiltrating lymphocytes of cancer patients and, to a lesser degree, in healthy individuals (Figure 2 below). When isolated and cultured *in vitro*, the self-reactive IDO- or PD-L1-specific T cells demonstrated proinflammatory and cytotoxic responses against IDO- or PD-L1-expressing target cells (Figure 3 below).





Key Components of Our T-win Technology T-win® Platform

Based on this discovery, we created our T-win technology platform to direct the immune system against, both tumor cells and genetically stable cells, within the TME that express immunosuppressive proteins, with the goal of transforming the immune balance within the TME.

The key elements of our T-win platform are:

- **Target selection**: We select targets based on well-documented immunosuppressive proteins that are known to be overexpressed in the TME across a wide range of tumors. Our target selection relies on the identification of T cell immunity against these key immune resistance pathways in the TME;
- **Epitope selection**: After a target is selected, the ability of the immune system to attack cells overexpressing immunosuppressive molecules is confirmed by examination of intrinsic T cell immunity. The initial epitope selection process involves screening peptide antigens, which are designed using both an *in silico* algorithm and our know-how for T cell reactivity in peripheral blood mononuclear cells derived from cancer patients across several indications. Upon identification of an immunogenic peptide antigen, the functionality of reactive T cells is then subjected to further testing to further evaluate whether activation leads to a favorable pro-inflammatory or anti-tumorigenic phenotype. Every T-win platform product candidate is designed to contain both $CD4^+$ and $CD8^+$ T cell epitopes that can be recognized over a wide range of patient population; and
- **Adjuvant**: T-win peptide product candidates are administered together with an adjuvant, such as Montanide. This provides protection to and facilitates effective release of our T-win peptide product candidates upon injection. It also causes local inflammation and facilitates recruitment of immune cells. This enables the antigen to be captured by antigen presenting cells and presented to T cells to drive their activation.

T-win Platform Mechanism of Action

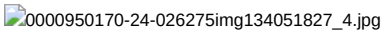
Our product candidates are designed to drive the activation and expansion of T cells reactive to immunosuppressive antigens. Upon trafficking these T cells into the tumor site, effective anti-tumor response is induced by a dual mode of action:

- Recognition and elimination of tumor cells; and
- Recognition and elimination of immunosuppressive cells.

We believe our T-win platform offers a novel approach that targets both tumor cells as well as genetically stable host immunosuppressive cells, in order to avoid immune escape. By attracting pro-inflammatory cells against immunosuppression within the TME, T-win product candidates are designed to alter the immunologically unfavorable TME environment into a pro-inflammatory milieu, thereby enhancing effective anti-tumor T cell responses. We believe that our T-win technology platform is the only existing platform that utilizes the intrinsic ability of cancer patients' own T cells to target immunosuppression in the TME.

Administration of our T-win product candidates via subcutaneous injection (Figure 4, step 1) selectively activates and expands pre-existing $CD4^+$ and $CD8^+$ T cell responses against the T-win product candidate targeted antigen, antigens, such as those derived from IDO, in the draining lymph nodes (Figure 4, step 2). The resulting T cells migrate to the tumor sites, where target cells with elevated expression of T-win product candidate targeted antigens are found in the TME. Upon recognition and engagement of the targeted cells, the T cells either directly eliminate the cells by cytotoxic lysis or respond by the release of proinflammatory cytokines (Figure 4, step 3). Elimination of immunosuppressive target cells and concomitant immune modulation of the TME into an inflamed environment results in net enhancement of T effector infiltration and enhanced anti-tumor responses (Figure 4, step 4).

Figure 4: Illustration of T-win T-win® Platform Mechanism of Action



Advantages of the T-win Technology Platform

We believe our T-win platform has the potential to pave the way for novel cancer vaccines with increased therapeutic effect and limited additional tolerability concerns. Potential advantages of our T-win platform include:

- **Durability of response: response**: T-win product candidates are designed to target not only tumor cells but also genetically stable healthy immunosuppressive cells, with the aim of avoiding immune escape. We believe that our approach of killing direct and indirect target killing targets may lead to immune memory, and thus sustained anti-tumor effect over time;
- **Dual and Multi-Epitope Design: Design**: In our product candidates, we often seek to include dual or multiple epitopes. The rationale behind this approach is based on the complexity of cancer, where individual patients suffering from the same cancer indication may have a different expression of immunoregulatory antigens and as a result may not respond to a single epitope treatment. We believe that an approach of targeting separate immune resistant pathways in the TME will enable our product candidates to address a larger pool of patients than therapies that are currently available therapies are able to reach;
- **Tolerability: Tolerability**: Therapies based on subcutaneously injected peptides have been observed to be well-tolerated in over 200 clinical trials. If T-win product candidates based on subcutaneously injected peptides are similarly well-tolerated, our product candidates could have the potential to be used as a component components of combination therapy in early treatment settings;
- **Versatility: Versatility**: Our product candidates based on our T-win platform have the potential to be used in combination with existing therapies such as checkpoint inhibitors, including the PD-1 monoclonal antibodies, pembrolizumab and nivolumab. As our product candidates target a range of immunosuppressive mechanisms mediated by proteins highly expressed among several cancer indications and the mechanism of action can potentially provide supplementary effect across different checkpoint inhibitors, we believe that the number of cancer indications and combination opportunities of our product candidates are extensive;
- **Well-understood manufacturing process: process**: The compounds necessary for the production of product candidates based on T-win technology platform are manufactured through a well-known synthetic chemistry process. We believe this enables us to reproduce high quality product at an anticipated low cost of goods; and
- **Ease of administration: Time to Treatment**: T-win product candidates are designed to be "off-the-shelf" treatments given subcutaneously on a flexible readily available, off-the shelf vaccines with the potential to provide immediate treatment schedule. These treatments can be adapted for specific cancer indications. compared to personalized approaches.

Current Trials

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Proposed Registrational Trial in Melanoma Under BTD by FDA

Based on the results of the MM1636 trial, we are recruiting recruited for a multicenter, international, open-label, randomized, two-arm Phase 3 potentially registrational trial of IO102-IO103, the IOB-013/KN-D18 trial, in combination with pembrolizumab as first-line treatment for patients with previously untreated unresectable or metastatic (advanced) melanoma. The Phase 3 trial has initially had a target enrollment of 300 patients randomized into either the experimental arm of IO102-IO103 in combination with pembrolizumab or the pembrolizumab control arm. As of June 2023, we had randomized 225 patients. In addition, on June 14, 2023, we announced that we increased enrollment in the IOB-013/KN-D18 study to 380 randomized patients; the trial reached full enrollment in November 2023. All patients will receive pembrolizumab 200 mg intravenously every three weeks for a maximum of 35 cycles, corresponding to approximately two years of treatment. Patients randomized to the experimental arm will also be given IO102-IO103 every three weeks with an additional dose given during the induction period on Day 8 of cycles 1 and 2. IO102-IO103 will thereafter be administered subcutaneously every three weeks during the maintenance period. Each patient can be treated for a maximum of 37 administrations in total, corresponding to approximately two years of treatment. An The Phase 3 trial protocol has a planned interim analysis of based on ORR that will be conducted one year 12 months after 75% of 225 patients have been randomized. The primary endpoint at randomized; if the final investigational arm demonstrates a highly statistically significant improvement in ORR compared to the control arm, with a p-value<0.005, then the interim analysis will be progression free survival. could allow for potential submission of a BLA for accelerated approval in the United States. When we designed the interim analysis, we assumed that patients treated with IO102-IO103 in combination with pembrolizumab would show an ~18-point improvement in ORR compared to the patients treated with pembrolizumab alone. The trial design and discussions with FDA are aimed at potentially pursuing accelerated approval, if the trial data are favorable, based on the interim analysis of ORR, supported by other data. If the data are supportive, we also plan to file an MAA with the EMA based on the primary endpoint of PFS after the data are available, which is expected to occur in the second half of 2025. The Phase 3 trial also includes a concurrent evaluation of the initial participants to allow for an assessment of safety, or safety run in.

Clinical Development in First-Line Indications

In addition to the IOB-013/KN-D18 trial discussed above, we are executing a Phase 2 basket trial, the IOB-022 trial, which will enable us to investigate multiple solid first-line tumor indications in anti PD-1/PD-L1 treatment naïve patients with metastatic disease, such as NSCLC UBC, and SCCHN. In the NSCLC portion of the trial we are investigating IO102-IO103 in patients expressing PD-L1 ≥50%, a patient population similar to Cohort A in our Phase 1/2 trial of IO102 in combination with pembrolizumab as first line treatment for patients with metastatic NSCLC.

Our IOB-022 trial is a non-comparative, open label, unblinded trial and investigates the safety and efficacy of IO102-IO103 in combination with pembrolizumab, intended to investigate each of the following metastatic first-line indications:

- NSCLC with PD-L1 TPS ≥50%
- SCCHN (HPV +/-) with PD-L1 CPS ≥20%

- The trial is ongoing in three countries (the United States, Spain and the United Kingdom) at 20 active sites.

Encouraging preliminary initial data was reported on August 21, 2023 for the first time from 28 lung cancer patients and 14 head and neck cancer patients in the Company's Phase 2 basket study (IOB-022/KN-D38) evaluating IO102-IO103 in combination with pembrolizumab in patients with non-small cell lung cancer and head and neck cancer as presented at the ESMO conference held in October 2023. Of the 28 patients enrolled in cohort A, 18 were efficacy evaluable per protocol having received at least two full cycles of treatment. Among the 18 evaluable patients, 10 patients had a partial response as their best overall response while 5 had stable disease and 3 patients had progressive disease. Of the 14 patients enrolled in cohort B, 6 were efficacy evaluable per protocol, having received at least two full cycles of treatment. Among the 6 evaluable patients, 3 patients had a partial response as their best overall response while 3 patients had progressive disease. The UBC cohort was closed in fiscal year 2023 in response to challenges in recruiting patients into the trial as a result of changes in standards of care associated with CPS ≥10%

UBC. The safety profile observed to date in this study is consistent with prior clinical experience with IO102-IO103. We anticipate reporting additional data from this study in 2024.

We reported encouraging initial Decisions regarding further clinical development and larger study plans will be made based on evaluation of data from the first 10 patients enrolled in the ongoing NSCLC cohort of this trial in January 2023. If the data from the initial 30 patients is supportive, we plan to first expand the sample size in Phase 2 and then pending the outcome move into a Phase 3 trial in one or more of these indications if a sufficiently strong efficacy signal is observed. SCCHN cohorts. The primary endpoints of the Phase 2 trial will be dual target of either ORR according to RECIST 1.1. or PFS at six months by investigator assessment. Secondary outcome measures will include PFS, duration of response, CRR, disease control rate, OS, time to response and safety reporting.

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Figure 5: Schematic Clinical Development Diagram

Diagram: IOB-022 Trial


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** KEYNOTE-042 (pembro alone in 1L NSCLC PD-L1 ≥ 50%): ORR 39% (Mok et al. Lancet 2019)*

*** KEYNOTE-48 (pembro alone in 1L SCCHN CPS PD-L1 ≥ 20%): ORR 23% (Burtness et al. Lancet 2019) EudraCT No. 2021-003026-69; ClinicalTrials.gov No. NCT05077709*

In addition to the IOB-022 trial, we have initiated a Phase 2 basket trial, the IOB-032 trial, to investigate IO102-IO103 in combination with pembrolizumab in a perioperative setting and used before or after surgery as a neo-adjuvant/adjuvant therapy in multiple solid tumor indications in anti-PD-1/PD-L1 naïve settings, focused initially on melanoma and SCCHN. In April 2023, the FDA cleared our IND application for the IOB-032 trial. We anticipate the study will initially enroll up to 15 patients with melanoma, and 15 patients with SCCHN.

The trial is currently enrolling patients in three five countries (US, Spain (Australia, the United States, France, Denmark, and the UK) Spain) at 21 14 active sites. All treatment arms are active and recruiting. Enrolling patients for the following cohorts are as follows:

- NSCLC Melanoma (n=17) 10-15)
- SCCHN (n=6) 15-20)

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- UBC (n=2)

Encouraging initial data was reported The primary endpoint of the study will be the percentage of patients with major pathologic response (MPR) in the resected tumor tissue after neoadjuvant treatment; secondary endpoints will be pathological CR and ORR; and other endpoints will be disease-free survival (DFS), event-free survival (EFS), and safety. We announced in a press release issued on January 9, 2023 for December 21, 2023 that the first time from 10 lung cancer patients patient in the company's Phase 2 basket IOB-032 trial was enrolled and dosed. In addition, we also filed a protocol amendment with the FDA in December 2023 to initiate enrollment of 30 new patients with resectable melanoma in a randomized cohort C study (IOB-022/KN-D38) evaluating in the IOB-032 trial. Patients in cohort C will be randomized 1:1 to receive the neoadjuvant treatment of either IO102-IO103 in combination with pembrolizumab or pembrolizumab alone, and will continue with the same regimen in patients the post-surgery phase. We are currently awaiting response from the FDA and, if the amendment is approved, we project that we will commence with non-small the amended protocol in the second quarter of 2024.

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Figure 6: Schematic Clinical Development Diagram: IOB-032 Trial


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** Recovery ≤ 12 weeks*

*** If required*

ECOG PS = Eastern Cooperative Oncology Group performance status; SCCHN, squamous cell lung cancer, carcinoma of the head and neck cancer, or bladder cancer. Of the 10, 9 were efficacy evaluable per protocol having received at least one full cycle of treatment. Among the 9 evaluable patients, 4 patients had a partial response while 4 had stable disease; one patient had progressive disease. The safety profile observed to date in this study is consistent with prior clinical experience with IO102-IO103. The company anticipates reporting additional data from this study in 2023.

If the data from the initial 30 patients is supportive, we plan to first expand the sample size in Phase 2 and then pending the outcome move into a Phase 3 trial in one or more of these indications if a sufficiently strong efficacy signal is observed. The primary endpoints of the Phase 2 trial will be dual target of either ORR according to RECIST 1.1. or PFS at six months by investigator assessment. Secondary outcome measures will include PFS, duration of response, CRR, disease control rate, OS, time to response and safety reporting neck; ClinicalTrials.gov No. NCT05280314

Our Product Candidates

We are developing a pipeline of product candidates that leverage our T-win technology T-win® platform to address targets within the TME. We are currently investigating IO102-IO103 in the IOB-013/KN-D18 trial, and the IOB-022 trial and we plan to initiate a Phase 2 basket trial, the IOB-032 of IO102-IO103 in combination with anti-PD-1 antibody therapy in the neo-adjuvant/adjuvant treatment setting in the second half of 2023. trial. We are also developing earlier stage product candidates that target additional

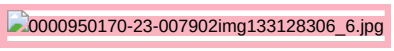
immunosuppression-related targets that are expressed in a broad range of solid tumors. tumors, which include our next product candidate, IO112, that targets Arginase 1 and the further development of a TGFβ1 vaccine, IO170. We expect to use these earlier stage product candidates in combination with our existing pipeline candidates.

Dual Epitope IO102-IO103

Our lead product candidate, IO102-IO103, combines our two fully-owned, novel immunotherapeutics, IO102 and IO103, which are designed to target IDO and PD-L1 expressing cells, respectively. IDO and PD-L1 are often dysregulated and over-expressed in a wide range of solid tumors, and result in the inhibition of the body's natural pro-inflammatory anti-tumor response within the TME. By combining IO102 and IO103 in a single treatment regimen, we aim to provide a synergistic effect on tumors. We are currently executing a Phase 3 potentially registrational trial in advanced melanoma for IO102-IO103, the IOB-013/KN-D18 trial, in combination with pembrolizumab.

IO102 contains a single IDO-derived peptide sequence and is designed to engage and activate IDO-specific T cells against IDO expressing cells within the TME. This contrasts to small molecule IDO inhibitors that aim to address tumors by inhibiting IDO pathways. IO103 contains a single PD-L1-derived peptide and is designed to engage and activate PD-L1 specific human T cells against PD-L1 expressing cells. This is in contrast to PD-1/PD-L1 antibodies which aim to counter T cell inhibition by blocking the interaction between PD-1 and its ligand. Through the activation of both IDO and PD-L1 activated T cells, IO102-IO103 is designed to directly kill immunosuppressive cells, including both tumor cells and genetically stable cells within the TME, and to reduce immunosuppression within the TME, in order to confer clinically meaningful and long lasting anti-tumor responses.

The following graphic illustrates the distinct approaches by which our T-win product candidates we hypothesized to engage with IDO expressing cells versus other clinically tested IDO inhibitors.



On December 14, 2020, the FDA granted us BTD for IO102-IO103 in combination with pembrolizumab for the treatment of patients with unresectable or metastatic melanoma based on data from the MM1636 Phase 1/2 clinical trial. BTD enables us to solicit guidance from the FDA on generating the clinical evidence needed to support approval in a expedited manner. The MM1636 trial was an investigator-initiated, single-arm Phase 1/2 trial of 30 anti PD-1/PD-L1 naïve patients with metastatic melanoma receiving IO102-IO103 and nivolumab, an anti-PD-1 monoclonal antibody. In this trial, investigators initially observed an ORR of 80% (24 out of 30 patients); however, two of 24 patients in which a response was observed progressed before subsequent radiological confirmation, which resulted in a confirmed ORR of 73%. In addition, 47% of patients achieved a CR, or complete elimination of their tumors based on RECIST 1.1 definitions. Based on the 17% discontinuation rate of treatment with both nivolumab and IO102-IO103, we believe that the data from this trial suggests a manageable tolerability profile for patients. In addition, we have observed treatment-induced infiltration of CD3/CD8 T cells into the tumor site in responding patients and detected IO102+IO103-specific T cells in tumors after treatment in correlative biomarker data where this was analyzed. We are currently recruiting for a Phase 3 potentially registrational trial for IO102-IO103, the IOB-013/KN-D18 trial, in combination with pembrolizumab. The Phase 3 trial also includes a safety run in.

IO102-IO103 specific T cells were found in the peripheral blood mononuclear cells (PBMCs) and at the tumor site.

Melanoma

IO102-IO103 is currently being tested in the IOB-013/KN-D18 in treatment-naïve patients with unresectable or metastatic (advanced) melanoma. Unresectable, metastatic melanoma is a serious and life-threatening disease with a clear unmet medical need. According to the American International Agency for Research on Cancer Society, of the World Health Organization, it was estimated that 325,000 patients were diagnosed with, and about 57,000 people would die from, melanoma worldwide in the United States in 2023, it is expected 2020. The agency further estimated that, approximately 100,000 510,000 patients will be diagnosed with, and about 8,000 96,000 people will die from, melanoma. melanoma, worldwide by 2040, representing an approximately 57% increase in new patients diagnosed with melanoma and an approximately 68% increase in melanoma related deaths. The incidence of cutaneous melanoma is also increasing, and advanced melanoma (unresectable or metastatic) is fatal if left untreated. According to Ascierto (JAMA Oncology 2019), Robert (New England Journal of Medicine 2019), and Larkin (New England Journal of Medicine 2019), and research conducted by the Melanoma Research Alliance, the median OS in patients with stage IV melanoma (untreated) regardless of BRAF mutation status is between 37-39 37 to 39 months and five-year OS is approximately 40-50% 22.5%. Anti-PD-1 monotherapy leads to a five-year OS of approximately 43-51%, while anti-CTLA-4 and anti-PD-1 combination therapy can increase five-year OS to approximately 52%, but is associated with

considerable toxicity. Accordingly, we believe there is a clear, unmet need for improved combination therapies with the potential to enhance anti-PD-1 efficacy without a significant increase in toxicity.

Historical and Current Standard of Care

Historically, chemotherapy, with or without interferon-alpha (IFN-a) (IFN-α) or IL-2, interleukin 2 (IL-2), was offered to patients with advanced melanoma, with limited results. Although in the last decade the treatment of advanced melanoma has improved with the regulatory approval of many novel agents, the current standard of care does not work for many patients. Before the availability of these treatments, according to Maio (Journal of Clinical Oncology 2015) and Garbe (The Oncologist 2011), patients with advanced melanoma had a median survival time of approximately 10 months. According to Robert (New England Journal of Medicine 2019) and Larkin (New England Journal of Medicine 2019), the current long-term survival is at least 37 to 39 months for patients with advanced melanoma regardless (regardless of BRAF mutational status status) based on current standard of care.

The currently approved novel agents can be divided into two main categories:

- **Immunotherapies**: Immune checkpoint inhibitors (CIs) targeting CTLA-4, such as ipilimumab, and PD-1, such as nivolumab and pembrolizumab, indirectly activate the immune system. The immune system plays an important role in the regulation of melanoma, and intravenously administered immunotherapies help overcome immune suppression; and
- **Targeted agents**: Orally administered selective inhibitors of mitogen-activated protein kinase (MAPK) directly inhibit the oncogene BRAF and MAPK pathway. According to Drummer (Lancet 2018), around 35-50% of advanced melanoma patients have a targetable BRAF mutation, and in approximately 90% of these cases, the mutation consists of valine substituted with glutamic acid at amino acid 600 (BRAF V600).

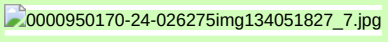
Recommended first-line treatment options for the treatment of unresectable or metastatic melanoma and for patients with or without BRAF-mutant advanced melanoma are summarized below:

- Anti-PD-1 monotherapy (nivolumab or pembrolizumab);
- Anti-CTLA-4 (ipilimumab) and anti-PD-1 (nivolumab) combination therapy;
- Anti PD-1 (nivolumab) and LAG-3 (relatlimab) combination therapy;
- Dabrafenib/trametinib combination targeted therapy if the activating BRAF-V600 mutation is present; and
- Vemurafenib/cobimetinib + atezolizumab combination targeted therapy and immunotherapy if the activating BRAF-V600 mutation is present.

Table 1a: Certain Currently Approved Immunotherapies and Targeted Agents

Clinical Trial	Treatment Arms	ORR	CRR	mDoR	mPFS	5-year PFS Rate	Median OS	5-year OS Rate	TRAEs leading to discontinuation
Immunotherapies									
CM-066 **3-y OS** (Ascierto et al. 2019)	Nivolumab	**43%**	**19%**	**N/A**	**5 mo**	**N/A**	**37 mo**	**51%**	**9%**
KN-006, IO naïve **5-y OS** (Robert et al. 2019)	Pembrolizumab	**46%**	**N/A**	**N/A**	**12 mo**	**27%**	**39 mo**	**43%**	**10%**
CM-067 **5-y OS** (Larkin et al. 2019)	Ipilimumab (3mg/kg)/ Nivolumab (1mg/kg)	**58%**	**22%**	**31 mo**	**12 mo**	**36%**	**> 60 mo**	**52%**	**42%**
	Nivolumab (3mg/kg)	**45%**	**19%**	**18 mo**	**7 mo**	**29%**	**37 mo**	**44%**	**13%**
RELA-047 (Tawbi et al 2022 *Long et.al. ASCO Plenary 2022)	Nivolumab (480 mg) and relatlimab (160 mg) Nivolumab (480 mg)	**43%*** **33%***	**16%*** **14%***	**N/A*** **N/A***	**10.1 mo** **4.6 mo**	**N/A**	**N/A**	**N/A**	**19%**
Targeted Agents									
COLUMBUS (Dummer et al. 2018)	Encorafenib/ binimetinib	**63%**	**8%**	**17 mo**	**15 mo**	**N/A**	**N/A**	**N/A**	**6%**
coBRIM (Ascierto et al. 2016)	Cobimetinib + vemurafenib	**70%**	**16%**	**13 mo**	**12 mo**	**N/A**	**22 mo**	**N/A**	**14%**

No head-to-head trials were conducted.



ORR: Overall response rate

CRR:	*Complete response rate*
PFS:	*Progression free survival*
OS:	*Overall survival*
mDoR	*Median duration of response*

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mo:	*months*
y:	*years*
NR	*Not reached*
N/A:	*Not available (including not reached numbers)*
TRAE:	*Treatment-related adverse events*

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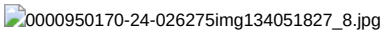
Table 1b: Selected Phase 3 Trial Update - American Society of Clinical Oncology (ASCO) 2022 2023



For patients with tumors harboring a BRAF V600 mutation, treatment choices are between MAPK or CI checkpoint inhibitor therapy. Cross trial comparisons indicate that combined MAPK or BRAF plus MAPK kinase (MEK) has proven to have higher response rates than CIs. checkpoint inhibitor therapies. Data from cross trial comparisons suggest that the responses to CIs checkpoint inhibitor therapies are slower in onset but more durable. For patients who are candidates for both treatments, standard of care guidelines recommend that CIs checkpoint inhibitor therapies should be chosen as first-line therapy. Patients whose tumors are not progressing quickly and are not immediately threatening an important organ function, should be considered for CIs checkpoint inhibitor therapies first, preserving MAPK for subsequent lines. However, American Society of Clinical Oncology guidelines do not recommend a specific order of therapies for patients with BRAF wild-type (WT) unresectable and metastatic cutaneous melanoma.

As combination therapy with ipilimumab/nivolumab is associated with more severe toxicity, physicians must make a treatment decision between combination therapy and single agent anti-PD-1 antibody therapy after thorough evaluation regarding clinical activity and potential severe toxicity. Accordingly, we believe novel anti-PD-1 combinations with improved overall outcomes are needed for patients with advanced melanoma.

We are developing IO102-IO103 for potential treatment of patients with anti PD-1 naïve in the advanced setting advanced melanoma who are candidates for CI monotherapy, regardless of PD-L1 expression and BRAF mutation status, except for patients with rapidly progressing disease. We also plan to test IO102-IO103 as a neo-adjuvant used before surgery, followed by adjuvant therapy after surgery, in patients with melanoma, in a basket trial, the IOB-032 trial, with multiple solid tumor indications. We announced that the first patient in the IOB-032 trial was enrolled and dosed in a press release issued on December 21, 2023.

Development of Dual Epitope IO102-IO103 in the First-line Setting

Summary

The MM1636 trial evaluated IO102-IO103 in combination with an anti-PD-1 monoclonal antibody, nivolumab, in 30 anti-PD-1 naïve, first-line metastatic melanoma patients. A brief summary of the MM1636 trial is below:

- 30 patients included in cohort A from Herlev University Hospital in Denmark; Denmark included in cohort A;
- Baseline characteristics were largely comparable with benchmark trials with the majority of patients having one or more poor prognostic factors, such as negative expression, M1c stage/visceral metastases and high lactate dehydrogenase (LDH);

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- Investigators initially observed an ORR of 80% (24 out of 30 patients); however, two of 24 patients in which a response was observed progressed before subs radiological confirmation, which resulted in a confirmed ORR of 73%. CRR was 50% with duration of response not yet reached at a median follow up time of 49.8 r

as of January 5, 2023;

- Median PFS was 25.5 months and median OS had not yet been reached as of January 5, 2023;

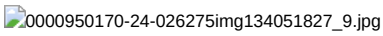
- Correlative biomarker data from the MM1636 trial support the mechanism of action of IO102-IO103 in treated patients, based on the following observations: observa
- Induction of systemic therapy (IO102+IO103)-specific T cell response in blood;
- Treatment-induced increased infiltration of CD3/CD8 CD3+/CD8+ T cells into the tumor site with enhanced immune effector signature in responding patients;
- Detection of IO102+IO103-specific IO102-IO103-specific T cells in tumors post treatment;
- 10 patients included in cohort B (patients with anti-PD-1 de-novo refractory disease) from Herlev University Hospital in Denmark; Denmark included in cohort B; and
- Enrollment 4 of 10 patients were enrolled into cohort C (patients with acquired anti-PD-1 resistance, meaning those who progressed after anti-PD-1 therapy), with enrollment completed in January 2023. Four of ten patients were enrolled into cohort C.

MM1636 Cohort A Trial Design and Patient Characteristics

The MM1636 trial consists of 3 cohorts – cohort cohorts A, B and C. Within each cohort, the trial was a Phase 1/2 single arm, single center trial with the primary objective to investigate safety and feasibility, secondary objective to investigate immunogenicity and tertiary objective to investigate clinical efficacy. While the size of the trial was deemed sufficient to evaluate safety, as a single arm trial, the MM1636 trial was not designed to provide statistically significant results in respect of its clinical efficacy endpoints. The MM1636 trial patients were treated with IO102-IO103 in combination with nivolumab for up to 47 weeks and thereafter continued with nivolumab treatment according to usual guidelines. Treatment consisted of 100 µg IDO long, 100 µg PD-L1 long1, 25 µl dimethyl sulfoxide (DMSO), 475 µl phosphate-buffered saline (PBS) and 500 µl Montanide. The treatment was administered biweekly for 6 weeks and then every 4 weeks for 41 weeks. Patients were given a maximum of 15 treatments during one year or until progression or undue adverse events. Nivolumab was administered according to the approved label for melanoma (3 mg/kg bi-weekly for up to two years). Because of the preclinical data on IO102-IO103, which provided support for the combination effect of our IDO and PD-L1 targeted candidates, IO102 and IO103, the MM1636 trial was not designed to evaluate the individual contributions of each component antigen.

A review of patient baseline characteristics presented in table 2 for the 30 anti PD-1 naïve metastatic melanoma patients prior to treatment included in cohort A of the MM1636 trial shows that the majority of patients had one or more poor prognostic factors; factors: 43% were PD-L1 negative, 60% with visceral metastatic disease (M1c) and 37% with high LDH. The frequency of these poor prognostic factors indicates that the patient population was not subject to specific selection of good prognosis patients, as the baseline characteristics are largely similar to those in other trials.

Table 2: MM1636 Cohort A—Patient Characteristics



Tolerability

In the MM1636 trial cohort A, 77% of patients developed Common Terminology Criteria for Adverse Events (CTCAE) grade 1 and 2 injection site reactions that typically manifested as transient adverse events; 77% experienced injection site tenderness, 63% experienced granulomas, 23% experienced redness, 13% experienced pain, 13% experienced pruritus, and 3% experienced myalgia at the injection site. The injection site reactions that manifested were most likely related to the adjuvant Montanide. Two patients discontinued treatment after eight and 11 injections, respectively, due to granulomas, tenderness and pain that limited instrumental activities of daily living. Other CTCAE grade 1-2 AEs have included rash (47%), fatigue (47%), arthralgia (30%), diarrhea (30%), nausea (23%), amylase increase (20%), dry skin (27%), pruritus (27%), infusion reaction (17%), xerostomia (17%) and myalgia (17%).

A total of five patients (17%) experienced a high-grade adverse event (grade 3-5); four patients (13%) experienced CTCAE grade 3-4 AEs, one patient with experienced a grade 3 maculopapular rash, one patient with had a grade 3 adrenal insufficiency and two patients with had a grade 3 arthralgia. One patient died (CTCAE grade 5) due to urosepsis with multi organ multi-organ failure and severe hyponatremia. In addition, the patient had experienced multiple AEs, including grade 3 colitis, grade 2 pneumonitis, grade 3 arthralgia, grade 2 vasculitis and grade 2 nivolumab induced infusion allergic reaction. The patient had symptoms of myocarditis at time of death with highly elevated troponin I. Bedside echocardiography showed an ejection fraction of 15%, which at baseline was 60%. The myocarditis was never confirmed pathologically. All the AEs leading to treatment

discontinuation were considered by the investigator to be related to nivolumab. The rate of treatment-related adverse events leading to discontinuation of both nivolumab and IO102-IO103 was 17%.

Response Rate in Cohort A

Results from the MM1636 trial, with a cut-off date of January 5, 2023, showed an ORR of 80% (95% confidence interval (CI); 62.7-90.5%). Two of the 24 responding patients progressed before subsequent radiological confirmation, therefore the confirmed ORR was 73.3% (95% CI; 54.1% to 87.7%). The CRR was 50.0% (95% CI; 31.3% to 68.7%).

Table 3: Objective Response Rate by Investigator Review

Date of data cut-off:	**January 5, 2023**
Median follow-up	49.8 months
Evaluable patients	30
Responders (including unconfirmed responses)	80.0% (N = 24)
Confirmed responders	22
Best Overall (confirmed) Response Rate (Clopper Pearson Exact 95% CI)	73.3% (N=22/30) 54.1% to 87.7%
Complete Response Rate (Clopper Pearson Exact 95% CI)	50.0% (N=15/30) 31.3% to 68.7%
Partial Response Rate (Clopper Pearson Exact 95% CI)	23.3% (N=7/30) 9.9% to 42.3%
Best overall (confirmed) response rate by PD-L1 status (PD-L1<1% vs □1%)	
PD-L1 positive patients (Clopper Pearson Exact 95% CI)	88.2% (N=15/17) 63.6% to 98.5%
PD-L1 negative patients (Clopper Pearson Exact 95% CI)	53.8% (N=7/13) 25.1% to 80.8%

Independent External Radiology Review

To substantiate the investigator assessed evaluation of efficacy, clinical response data was validated by blind independent external review. This was performed at an earlier cut-off date (January 2020) where an ORR of 76.7% (CI: 57.7%-90.1%) was reported with 50.0% achieving CR, 26.7% partial response (PR), and 3.3% stable disease.

Comparison With Contemporary anti PD-1 Treated Patients from the National Danish Metastatic Melanoma Database (DAMMED)

To address potential trial bias regarding treatment effect through post-hoc exploratory analysis, patients in the MM1636 trial were matched with patients from the Danish Melanoma Database (DAMMED), which is a population-based database that retrospectively collects data on patients with metastatic melanoma in Denmark.

- Data regarding 938 patients who were treated with a PD-1 therapy monotherapy contemporaneously (January 2015 to October 2019) were was extracted. 218 of patients were eligible for comparison and matching (all parameters available). 60 DAMMED patients were found to match;
- Patients were matched on age (□70, > 70), gender, LDH (normal, elevated), M-stage (M1a, M1b, M1c), BRAF status (Wildtype, mutated) and PD-L1 status (<1, □ 1). An exact matching algorithm was used where patients in the MM1636 trial were matched with patients from DAMMED with the exact same combination of variables;

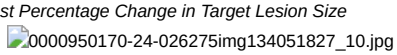
- 29 patients from the MM1636 trial were matched with the exact combinations of the six variables. One patient could not be matched. To secure a balance calculations, control patients were weighted according to the number of patients for each MM1636 patient. Estimates for treatment effects were calculated by we logistic regression analyses and weighted Cox proportional hazard model. A weighted binary logistic regression model was used for comparing response rates in t matched cohorts; and
- Matched controls were identified for 29 patients and the ORR of 79.3% (95 CI: 61.0-90.4%) observed in the MM1636 trial was found to be significantly higher (p<0 compared to the matched control group where an ORR of 41.7% (95% CI: 31.0-53.3% 31.0% to 53.3%) was reached. Furthermore, of the 29 patients in the MM163 a significantly (p<0.0017) higher percentage of 41.4% (CI: 25.2-59.6% 25.2% to 59.6%) patients achieved CR in the MM1636 trial, compared to 12% (CI: 6.3-21.6% to 21.6%) in the matched historical control group.

The ORR was significantly higher in the patients from the MM1636 trial than in the historical controls, suggesting that the high response rate and the long durability of response observed with the combination therapy approach are unlikely to be due to patient selection bias.

Tumor Shrinkage in Individual Patients in Cohort A

Data showing the percent change in target lesions from the baseline is shown in Figure 6. The effect was binary, as patients either responded (24 out of 30) or progressed experienced disease progression (six out of 30). No patients showed stable disease (SD). The icons describe melanoma risk factors. Green bars indicating CR that are not at 100% tumor reduction are in patients with lymph node metastases, as lymph nodes do not disappear but normalize in size. Blue and green bars at 100% indicate the disappearance of target lesions, whereas some non-target lesions may remain based on RECIST 1.1. definitions. Six of the 30 patients progressed (red experienced disease progression (orange bars).

Figure 6: MM1636 Cohort A—Waterfall Plot Showing Best Percentage Change in Target Lesion Size



CR = complete response, PR = partial response, PD = progressive disease

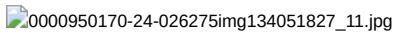
Timing and Durability of Response in Individual Patients in Cohort A

The swimmer plot in Figure 7 below presents individual patient-level data, including onset of PR, CR, PD and death. In addition, patients with ongoing responses as of the January 5, 2023 cut-off date are marked with an arrow. As of the January 5, 2023 cut-off date, response was still ongoing in 10 patients. The majority of patients achieving a CR had one or more high risk factors (marked with icons) such as PD-L1 negative tumor expression, M1c stage/visceral metastases and high LDH as an indication severe disease. As of the January 5, 2023 cut-off date, response was still ongoing in 10 patients (indicated with arrows).

CRs have been were observed more than 15 months after initial treatment, and as of the January 05, 2023 January 5, 2023 cutoff date, the CRR has had improved to 50% as for the latest included patients with a minimum follow-up of 30 months. We believe these data indicate good quality responses with a deep and durable response in most of the patients (Figure 8).

The median duration of response (DOR) was 27 months as of the January 05, 2023 January 5, 2023 cut-off date in the MM1636 trial, and 20 of the 22 patients with a radiologically confirmed response (at 12 weeks after the first response) had a response lasting greater than 182 days providing a durable response rate of 66.7% (20/30). (Figure (Figures 7 and 8).

Figure 7: MM1636 Cohort A—Durability and Deepening Responses



CR = complete response, PR = partial response, PD = progressive disease

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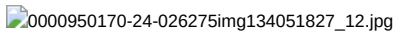
Figure 8: MM1636 Cohort A—Duration of Response



Tumor shrinkage Shrinkage and Durability of Response in Individual Patients Over Time in Cohort A

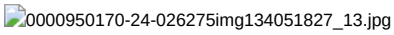
The rapid onset of response, deepening of responses over time and durability of responses in the MM1636 trial are shown in the spider plot for individual patients. Green, blue and red lines respectively indicate CR, PR and PD. Only six out of 30 patients experienced progressive disease at the first imaging timepoint (12 weeks) marked with red lines

(Figure 8).

27

25

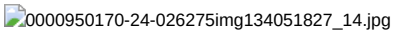
Figure 9: MM1636 Cohort A—Change in Target Lesions from Baseline Over Time



Progression Free Survival (PFS) in Patients from Cohort A

At a median duration of follow-up of 49.8 months (Figure 10), the median PFS was 25.5 months.

Figure 10: MM1636 Cohort A—Progression Free Survival



+ Censored; dotted lines show 95% Confidence Limits

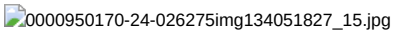
Overall Survival (OS)

28

26

At a median duration of follow-up of 49.8 months, the median OS had still not yet been reached (Figure 11).

Figure 11: MM1636 Cohort A—Overall Survival



+ Censored; dotted lines show 95% Confidence Limits

Phase 1/2 Correlative Data

Correlative biomarker data from the MM1636 trial support the mechanism of action of IO102-IO103 in treated patients, based on the following observations:

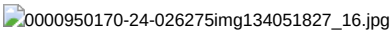
- Induction of systemic therapy (IO102+IO103)-specific T cell response in blood was confirmed in over 96% of treated patients (Table 4);
- Confirmation of IO102-IO103-specific T cell clones homing into TME (Figure 12); and
- Treatment-induced increased infiltration T cells into TME with enhanced immune effector signature in responding patients (Figure 13).

Table 4: Treatment-specific T cell Responses to IO102 (IDO) and/or IO103 (PD-L1)

	T-win T-win® antigen-specific response at BASELINE	T-win antigen-specific response ON-TREATMENT
Response against IO102	10/30 (33.3%)	27/30 (90%)
Response against IO103	8/30 (26.7%)	25/30 (83.3%)
Response against IO102 and/or IO103	14/30 (46.7%)	29/30 (96.7%)

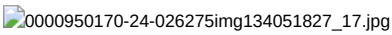
27 29

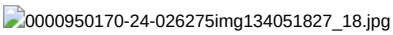
Figure 12: Increased Frequency of IO102-IO103-expanded T cell Clones Detected in TME After Treatment.Treatment



Cumulative frequencies of IO102-IO103-specific TCR rearrangements pre- and post-treatment in one CR patient are shown.

Figure 13: Treatment-induced Increased Infiltration T cells into TME with Enhanced Immune Effector Signature in Responding Patients





(A) In a CR patient (PD-L1 negative, LDH high, BRAF WT, M1c), immunohistochemistry (IHC) analysis of tumor sections before vs on-treatment revealed more than three-folds increase in infiltrating T cells (left), majority of which were antigen-experienced (positive for PD-1/LAG-3/T cell immunoglobulin and mucin domain-containing protein 3 (TIM-3), "Ag+ CD8+" "Ag^+ $CD8^{+"}$) $CD8^+$ T cells (right). (B) This was accompanied by increased signature of effector T cell activation with concomitant reduction in pro-tumorigenic genes.

MM1636 Cohort B

Ten patients with metastatic melanoma with progressive disease on anti-PD-1 therapy were enrolled from May 2019 to September 2022. A review of patient baseline characteristics for the 10 patients with refractory (to an anti PD-1 therapy) melanoma who were included in cohort B of the MM1636 trial shows all patients to have BRAF wild-type tumors, and 50%

with available PD-L1 status (n=8) were PD-L1<1%. Nine of the patients had normal LDH levels and two patients had disease stage M1c. The mean age was 68.5 years.

As of the January 5, 2023 data cutoff, all patients were off trial treatment due to progressive disease. The most frequently reported adverse events as considered related to nivolumab were CTCAE grade 1-2 fatigue (30%), nausea (30%) and dry skin (30%). Local injection site reactions were seen in 40% of the patients.

In terms of efficacy, the best overall response was stable disease in 2 (20%) patients and eight were progressive disease. The mOS was 16.7 months and the mPFS was 2.4 months.

In summary, patients who were PD-1 refractory and enrolled in cohort B in this study had no response to therapy, which we believe shows that our vaccine works best in front-line metastatic melanoma patients, as we expected in this setting.

Potential Opportunities for Dual Epitope IO102-IO103

Lung Cancer

Lung cancer is the leading cause of cancer death according to the American Cancer Society (ACS). The two main types of lung cancer are NSCLC and small cell lung cancer (SCLC). Worldwide, lung cancer is the second most diagnosed cancer and NSCLC is the most common type estimated to account for 85% of all lung cancer accounting for about 84% of all cases. diagnoses. According to the ACS, International Agency for Research on Cancer of the World Health Organization, it was estimated that 1,875,000 patients were diagnosed with, and about 1,526,000 people would die from, NSCLC worldwide in 2020. The agency further estimated that, by 2040, approximately 3,084,000 patients will be diagnosed with, and about 2,557,000 people will die from, NSCLC, representing a 64% and 68% increase in new patients diagnosed with NSCLC and NSCLC related deaths, respectively. According to the organization, the five-year survival rate for patients suffering from highly advanced, metastatic (Stage IV) lung cancers is estimated to be 6% 28%. The NSCLC market was expected to generate $28.5 billion $45.5 billion in revenue in 2021, 2022, growing to $48 billion $81.4 billion in 2026.2028 with a compounded annual growth rate (CAGR) of 10%.

There is a large unmet need for improved combination therapies enhancing anti-PD-1 efficacy without a significant increase in toxicity. Until recently, the standard of care for patients with metastatic NSCLC was platinum-based chemotherapy. Recently, anti-PD-1 therapy, such as pembrolizumab, with or without chemotherapy, has changed the standard practice in first-line treatment of metastatic NSCLC. According to Mok (Lancet 2019) and Gandhi (New England Journal of Medicine 2018) the ORR with pembrolizumab monotherapy in for patients with previously untreated metastatic NSCLC and a PD-L1 expression of 50% or higher who were treated with pembrolizumab monotherapy was 39%

and pembrolizumab in combination with chemotherapy 61%. In high PD-L1, approximately 40% of patients are alive after 30 months on pembrolizumab monotherapy. In low PD-L1, approximately 45% of patients are alive at 24 months on pembrolizumab plus chemotherapy.

Observations from a Phase 1 trial of our first generation IDO compound, IO101, provided us foundational support for our IO102-IO103 development strategy. We have initiated development of IO102-IO103 plus anti PD-1 in first-line treatment of metastatic solid tumors with high PD-L1 expression. NSCLC is one of the indications in our IOB-022 basket trial. Consistent with the earlier reported data and as presented at the ESMO conference in October 2023, preliminary results from the IOB-022/KN-D38 Phase 1/2 study of IO102-IO103 in combination with pembrolizumab in metastatic NSCLC continue to be encouraging. As of August 21, 2023, of the 28 patients enrolled in cohort A, 18 were efficacy evaluable per protocol having received at least two full cycles of treatment. Among the 18 evaluable patients, 10 patients had a partial response as their best overall response while 5 had stable disease and 3 patients had progressive disease.

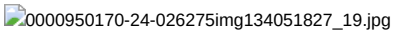
First Generation IDO Compound

LU1006 was an investigator-initiated Phase 1 single-arm, first-in-human trial with the primary objective of investigating safety, the secondary objective of investigating immunogenicity, and the tertiary objective of investigating clinical benefits in patients with heavily pretreated human leukocyte antigen-A2 (HLAA2) positive stage III to IV NSCLC. Patients had stable disease after standard therapy comprising of chemotherapy and targeted therapy. The trial was a non-randomized comparison against patients who had standard of care, chemotherapy, at the site and were HLAA2 negative. 15 patients were treated with IO101 as subcutaneous injections formulated in 900 microliters Montanide and imiquimod ointment. The mean treatment duration was 7.9 months (95% CI: 4.6 –11.3).

Tolerability

In 90% of the patients in the LU1006 trial, CTCAE grade 1 to 2, short-term, local injection site reactions (i.e., redness, swelling, or itching) were observed. Local treatments with steroid ointments removed the symptoms. High frequencies of fatigue, shortness of breath, coughing and hemoptysis were present at baseline in the 15 NSCLC patients. These were considered to probably be related to the underlying lung cancer. Nausea and headache were observed in relation to the development of brain metastases, whereas dyspepsia, abdominal pain and diarrhea could be related to the treatment, as IDO is expressed in the epithelial cells in the gastrointestinal tract (Table 5). No grade 3 or higher AEs were observed in the 15 patients treated with IO101 monotherapy.

Table 5: Adverse Event Frequency by CTCAE Grade



Clinical Benefit

Clinical benefit was defined as OR or SD for a minimum of 8.5 months after treatment initiation, corresponding to at least nine injections and demonstration of SD on at least three consecutive CT scans. Based on this definition, seven of 15 (47%) patients had clinical benefit. One patient achieved a PR after 15 months treatment (ORR of 7%), and six patients obtained SD (40%).

Survival

Progression-free survival (PFS) is shown in Figure 14 below. “Censored” represents patients who are surviving without progression of disease. The median PFS was 5.2 months. Overall survival was 26 months in the 15 patients treated with IO101, compared to eight months in patients who received the hospitals standard of care, which included chemotherapy and targeted therapies. These observations provided us foundational support for our IO102-IO103 development strategy.

Figure 14: IDO Monotherapy—Progression Free Survival

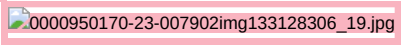
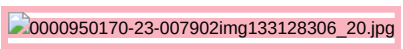


Figure 15: IDO Monotherapy—Overall Survival

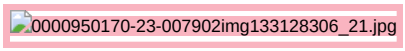


Long Term Follow-Up

According to Kjeldsen (2018), three of 15 patients were still alive at a five-year follow up corresponding to a six-year overall survival of 20%. Two patients had continued monthly injections for five years (56 injections). One of these patients developed a PR 15 months after the first injection and remained in PR, without other subsequent anti-cancer therapy.

The other patient had a solitary distant metastasis in a retroperitoneal lymph node at baseline which normalized during treatment. All on study CT scans were without signs of relapse. Treatment was well tolerated for up to five years with no long-term AEs registered. The third long-term surviving patient discontinued treatment after 11 months due to PD. The chart below shows the duration of response for patients receiving study drug.

Figure 16: IDO Monotherapy—Duration of Response

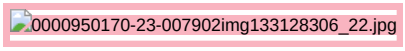


Second Generation IDO Compound (IO102)

Our second generation IDO compound, IO102, was tested in an fully recruited, open-label, randomized Phase 1/2 trial in combination with pembrolizumab (Cohort A) or pembrolizumab with chemotherapy (Cohort B) as first-line treatment for patients with metastatic NSCLC. The trial had a Phase 1 safety run-in and Phase 2 is randomized (Figure 17). The primary

objectives were to investigate the safety and efficacy of IO102 as an add on to standard of care versus standard of care. Primary endpoints were safety and ORR. Secondary endpoints include OS, PFS and biomarkers.

Figure 17: IO102-012 Trial Design



The trial was conducted as part of a clinical collaboration with Merck. The clinical trial was sponsored by IO Biotech while Merck provided pembrolizumab for the trial. Merck and IO Biotech have joint rights to the study results. IO Biotech will maintain global commercial rights to IO102.

Results presented below are from an updated analysis of patients entered into the Phase 2 part of the study, with a data cutoff of August 11, 2021. At this data cut off, a total of 110 patients were included in the trial, of which 109 received treatment. Six patients each in Phase 1 cohort A and B; 32 patients in the experimental arm A1 (IO102 with pembrolizumab), 16 patients in the control arm A2 (pembrolizumab); 33 in the experimental arm B1 (IO102 with pembrolizumab and chemotherapy) and 17 in the control arm B2 (pembrolizumab with chemotherapy) of which 16 were treated.

At the data cutoff, based on RECIST 1.1 definitions, Phase 2 Cohort A patients in the experimental arm achieved ORR of 46.9% and 43.8% in the control arm. In Phase 2 Cohort B, patients in the experimental arm achieved ORR of 36.4% and 52.9% in the control arm.

In the NSCLC portion of the IOB-022 trial, we plan to investigate IO102-IO103 in patients expressing PD-L1 ≥50%.

Tolerability Profile

The tolerability profile presented is for patients entered and treated in the Phase 2 part of IO102-012 (the safety population):

Cohort:	Experimental Arm N	Control Arm N	Total
A: PD-L1≥50%	32	16	48
B: PD-L1<50%	33	16	49

Table 6 summarizes the AEs reported as of the more recent data cutoff in August 2021.

All patients (100%), regardless of treatment allocation, had at least one treatment emergent adverse event (TEAE).

Cohort A (PD-L1 ≥50%): 81% of patients in the experimental arm (A1) and 81% administered pembrolizumab (A2) had at least one treatment related AE. 69% of patients in A1 had AEs related to IO102. The corresponding number for treatment related AEs to pembrolizumab were 79% across both arms. Serious AEs (SAE) were reported in 41% and 31% of the patients and related treatment-related SAEs in 9% and 0%, respectively. High grade AEs (CTCAE grade 3-4) were reported in 53% and 63% of patients, with 6% and 13%, respectively of the patients discontinuing any of the treatment due to TEAEs. Fatal (grade 5) AEs occurred in 3% and 6%, respectively.

Cohort B (PD-L1 <50%): 97% of patients in the experimental arm (B1) and 100% administered pembrolizumab and chemotherapy (B2) had at least one treatment related AE. 67% of patients in B1 had AEs related to IO102. The corresponding number for treatment related AEs to pembrolizumab and were 82% across both arms. Serious AEs (SAE) were reported in 42% and 56% of the patients and related SAEs in 18% and 31%. High grade AEs (CTCAE grade 3-4) were reported in 73% and 94% with 33% and 19%, respectively, of the patients discontinuing any of the treatments due to TEAEs. Fatal (grade 5) AEs occurred in 9% and 0%, respectively.

Table 6: Adverse Events Summary, Cohort A & B, Phase 2

	Cohort A			Cohort B		
	Experim A1	Control A2	Total	Experim B1	Control B2	Total
Number of patients	N=38	N=16	N=54	N=39	N=16	N=55
Number of patients with at least one						
TEAE	32 (100%)	16 (100%)	48 (100%)	33 (100%)	16 (100%)	49 (100%)
Related TEAE (any study treatment)	26 (81%)	13 (81%)	39 (81%)	32 (97%)	16 (100%)	48 (98%)
TEAE related to IO102	22 (69%)	—	22 (46%)	22 (67%)	0 (0%)	22 (45%)
TEAE related to Pembrolizumab	25 (78%)	13 (81%)	38 (79%)	25 (76%)	15 (94%)	40 (82%)
TEAE related to Carboplatin	—	—	—	30 (91%)	15 (94%)	45 (92%)
TEAE related to Pemetrexed	—	—	—	31 (94%)	16 (100%)	47 (96%)
Serious TEAE	13 (41%)	5 (31%)	18 (38%)	14 (42%)	9 (56%)	23 (47%)
Serious related TEAE (any study treatment)	3 (9%)	—	3 (6%)	6 (18%)	5 (25%)	11 (22%)
Grade 3 or 4 TEAE	17 (53%)	10 (63%)	27 (56%)	24 (73%)	15 (94%)	39 (80%)
TEAE leading to discontinuation of any study treatment	2 (6%)	2 (13%)	4 (8%)	11 (33%)	3 (19%)	14 (29%)
TEAE leading to discontinuation of IO102	2 (6%)	—	2 (4%)	6 (18%)	—	6 (12%)
TEAE leading to discontinuation of Pembrolizumab	2 (6%)	2 (13%)	4 (8%)	6 (18%)	2 (13%)	8 (16%)
TEAE leading to discontinuation of Carboplatin	—	—	—	0 (0%)	1 (6%)	1 (2%)
TEAE leading to discontinuation of Pemetrexed	—	—	—	10 (30%)	3 (19%)	13 (27%)
TEAE leading to dose interruption of Pembrolizumab	12 (38%)	10 (63%)	22 (46%)	22 (67%)	9 (56%)	31 (63%)
Fatal TEAE	1 (3%)	1 (6%)	2 (4%)	3 (9%)	—	3 (6%)

The distribution of high-grade AEs (CTCAE grade 3 or higher, including fatal) is shown below.

Cohort A (PD-L1 □50%): The most frequent high-grade AEs in cohort A1 (experimental, N=32), were infections, 18.8%, followed by vascular disorders, 15.6%. In A2 (control, N=16) the most common high grade AE was infections and infestations reported in 25.0% of patients.

Cohort B (PD-L1 <50%): The most frequent high-grade AEs in cohort B1 (experimental, N=33), were blood and lymphatic system disorders, in 39.4% of patients with 62.5% experiencing blood and lymphatic system disorders in B2 (control, N=16).

When comparing the experimental treatment in Cohort A and B with the control treatment, the safety data appears largely comparable, which suggests there was no increased frequency or severity of adverse events compared with the control arm.

Table 7.1: AEs □ Grade 3 in at Least 5% of Patients/Cohort (Phase 2)

System Organ Class	A1 32	A2 16	B1 33	B2 16
Blood and lymphatic system disorders	2 (6.3%)	0 (0%)	13 (39.4%)	10 (62.5%)
Cardiac disorders	3 (9.4%)	0 (0%)	0 (0%)	1 (6.3%)
Gastrointestinal disorders	1 (3.1%)	0 (0%)	4 (12.1%)	3 (18.8%)
General disorders and administration site conditions	0 (0%)	2 (12.5%)	5 (15.2%)	1 (6.3%)
Hepatobiliary disorders	0 (0%)	0 (0%)	1 (3.0%)	0 (0%)
Infections and infestations	6 (18.8%)	4 (25.0%)	8 (24.2%)	4 (25.0%)
Injury, poisoning and procedural complications	1 (3.1%)	0 (0%)	1 (3.0%)	0 (0%)
Investigations	3 (9.4%)	0 (0%)	4 (12.1%)	3 (18.8%)
Metabolism and nutrition disorders	2 (6.3%)	3 (18.8%)	3 (9.1%)	1 (6.3%)
Musculoskeletal and connective tissue disorders	1 (3.1%)	0 (0%)	3 (9.1%)	0 (0%)

Neoplasms benign, malignant and unspecified	2 (6.3%)	1 (6.3%)	0 (0%)	0 (0%)
Nervous system disorders	0 (0%)	0 (0%)	3 (9.1%)	1 (6.3%)
Renal and urinary disorders	0 (0%)	2 (12.6%)	1 (3.0%)	0 (0%)
Respiratory, thoracic and mediastinal disorders	3 (9.4%)	3 (18.8%)	3 (9.1%)	0 (0%)
Vascular disorders	5 (15.6%)	1 (6.3%)	2 (6.1%)	0 (0%)

Adverse events experienced by □5% of patients entered into Phase 1 are provided below (date of data cutoff March 12, 2021).

Table 7.2: AEs □ Grade 3 in at Least 5% of Patients/Cohort (Phase 1)

System Organ Class	A: IO102+pembrolizumab n=6	B: IO102+pembrolizumab+ chemotherapy n=6
Blood and lymphatic system disorders	0 (0%)	4 (66.7%)
Cardiac disorders	0 (0%)	0 (0%)
Gastrointestinal disorders	1 (16.7%)	0 (0%)
General disorders and administration site conditions	0 (0%)	1 (16.7%)
Infections and infestations	0 (0%)	1 (16.7%)
Investigations	1 (16.7%)	0 (0%)
Metabolism and nutrition disorders	0 (0%)	2 (33.3%)
Musculoskeletal and connective tissue disorders	1 (16.7%)	0 (0%)
Neoplasms benign, malignant and unspecified	0 (0%)	0 (0%)
Nervous system disorders	0 (0%)	0 (0%)
Renal and urinary disorders	0 (0%)	0 (0%)
Respiratory, thoracic and mediastinal disorders	1 (16.7%)	1 (16.7%)
Skin and subcutaneous tissue disorders	1 (16.7%)	0 (0%)
Vascular disorders	0 (0%)	0 (0%)

Squamous Cell Carcinoma of the Head and Neck Cancer (SCCHN)

SCCHN includes cancers of the oral cavity, oropharynx, hypopharynx and larynx, and is one the sixth most diagnosed cancer worldwide. According to the International Agency for Research on Cancer of the most common tumor types worldwide. Each year World Health Organization, it was estimated that 744,000 patients were diagnosed with, and about 364,000 people would die from, SCCHN worldwide in 2020. The agency estimated that, approximately 1,109,000 patients will be diagnosed with, and about 556,000 people will die from, SCCHN by 2040, representing a 49% and 52% increase in new patients diagnosed with SCCHN and SCCHN related deaths, respectively. According to the United States, cancers of organization, the oral cavity, oropharynx, hypopharynx and larynx are expected five-year survival rate for patients suffering from SCCHN was estimated to occur in more than 66,600 patients and more than 14,600 are expected to die. be 50%. Locoregional SCCHN is treated with curative intent, but at a cost of functional impairment and locoregional recurrence or metastatic disease.

Standard first-line treatment for recurrent or metastatic (R/M) disease that is not amenable to local therapy was for more than a decade, cetuximab, an anti-epidermal growth factor receptor (EGFR) antibody, plus chemotherapy with platinum and 5-fluorouracil (the EXTREME regimen), which provides a mOS of about 10 months and is associated with substantial adverse events, according to Vermorken (New England Journal of Medicine 2008).

According to Burtness (Lancet 2019), in the KN-048 Phase 3 clinical trial, mOS with pembrolizumab was 12.3 months in patients with combined positive score (CPS) > 1% and 14.9 months in CPS > 20% versus 10.7 months and 10.3 months with the EXTREME regimen. In the overall population, the mOS with pembrolizumab plus chemotherapy was 12.3 months versus 10.7 months with EXTREME. Based on the above, pembrolizumab plus platinum and 5-fluorouracil is an appropriate first-line treatment for

R/M SCCHN and pembrolizumab monotherapy is an appropriate first-line treatment for PD-L1-positive recurrent or metastatic SCCHN. Pembrolizumab with or without chemotherapy did not improve the ORR versus EXTREME. ORR ranged from 17 to 23% with pembrolizumab versus 35-36% with EXTREME, pending on the CPS.

A significant number of cancer patients fail to respond to immunomodulatory agents regardless of PD-L1 expression, presumably because of tumor resistance mechanisms against immune attacks. According to Burtness (Lancet 2019), the two year OS in first-line R/M SCCHN ranged from 38% to 27%, pending on the CPS. Consequently, there is a

large unmet need for improved combination therapies enhancing anti-PD1 efficacy without an increase in toxicity.

Besides anti-PD-1, investigations into the immune landscape of SCCHN provide a strong rationale to test agents targeting other immunomodulatory pathways such as IDO and arginase, either as a monotherapy or in combination with other therapies.

The In the United States, the head and neck cancer market was expected to generate $3 billion $2.9 billion in revenue in 2021 2022 and is expected to grow to $5.8 billion $4.7 billion by 2026.2028, reflecting a CAGR of 8%.

- We are planning As part of the IOB-032 trial, we commenced another development track in curative settings with neo-adjuvant (before surgery or radiotherapy)/ac treatment (after surgery or radiotherapy). SCCHN may be is one of these indications.
- We are also investigating the dual epitope strategy in first-line setting of previously untreated solid tumors. Recurrent or metastatic (R/M) R/M SCCHN is one of indications.

The ongoing and planned investigator-initiated trials will provide learnings that we can use in our own development of IO102-IO103. See "—Additional trials in other first-line indications and neo-adjuvant and adjuvant settings" for additional details on these trials.

Development of Dual Epitope IO102-IO103 in Neo-Adjuvant/Adjuvant Settings

One ongoing investigator-initiated trial at the St Luc Hospital in Belgium (HN1901) is testing the effect of single epitopes (IO102 and IO103) and later dual epitopes (e.g. IO102-IO103) as neo-adjuvant therapy (before surgery) on the TME in a randomized Phase 2 Umbrella trial in patients with resectable SCCHN. Treatment is short term with up to 3-4 weekly injections and patients are randomized against no treatment (observation before surgery as standard of care).

The primary objective is to evaluate T cell epitope specific response in blood after injections and the secondary objectives include safety, tolerability and anti-tumor effects of the epitopes tested. Translational Research will also be investigated (see Table 10 below). As of an August 2021 data cutoff, seven patients were enrolled in the HN1901 trial – four in the IO102 single epitope treatment arm and three patients in the control arm (where no treatment prior to surgery is received). The four IO102-treated patients had an aggregate of five primary tumors. Of these tumors, two tumors changed from an intermediate to a high immunoscore, a measure of how well a body's immune cells surround and enter a tumor, two tumors remained unchanged, and one tumor had a reduced immunoscore. In the control arm, two patients maintained a stable immunoscore and one patient went from a high to intermediate immunoscore. In the IO102 treatment arm, only CTCAE grade 1-related adverse events were recorded. No serious adverse events related to the study drug were reported. No delays in standard treatment due to side effects were observed. Among the IO102-treated patients, diffusion imaging analysis showed a decrease in the median apparent diffusion coefficient (mADC) after treatment in two patients (-11% and -14%) but not in one patient. One evaluable patient in the control arm did not show changes in mADC. Diffusion imaging analysis was not conducted for one patient in the IO102 treatment arm and for two patients in the control arm.

Another investigator-initiated trial in SCCHN is planned at an academic site in the U.S. This trial will investigate dual epitope (IO102-IO103) therapy in combination with anti PD-1 as neo-adjuvant therapy before surgery followed by adjuvant therapy after surgery in patients with SCCHN.

Urothelial Bladder Cancer

UBC is a common malignancy, and was expected to occur in almost 84,000 patients in the United States in 2021. It was expected to account for approximately 17,200 deaths in 2021. In the vast majority of patients, tumors are of the transitional cell subtype. Similar to other malignancies, UBC has a high rate of survival if diagnosed early (>90%); however, even regional spread results in a decline in the five-year survival rate to under 50%. Approximately 75% of newly diagnosed cases of bladder cancer in the United States are early stage and non-muscle invasive disease. Low grade Ta lesions and high-grade T1 lesions have similar recurrence rates near 50%; however, high grade T1 lesions have a higher chance of progression than Ta lesions.

While a majority of cases treated with bladder cancer have a favorable prognosis, non-muscle invasive bladder cancer (NMIBC) represents a heterogenous group of diseases to which risk stratification is important to further prognosticate and guide management. Multiple efforts have been made to risk stratify patients, and NMIBC is generally classified into low, intermediate, and high-risk (T1, high-grade Ta, or carcinoma in situ/Tis) groups (Table 8). Despite continued Bacillus Calmette-Guérin (BCG) therapy, high risk groups have over a 30% recurrence risk at year one and an over 50% recurrence chance at year five. Moreover, disease progression rates are nearly 20% in high risk patients. Patients who do experience disease progression often must undergo radical cystectomy, an invasive procedure with high mortality rates.

Atezolizumab and pembrolizumab are both approved first-line agents in the metastatic setting and avelumab is approved as maintenance after first-line chemotherapy. Pembrolizumab furthermore has an indication in NMIBC refractory to BCG therapy, as previously discussed. Therefore, targeting the PD-L1 pathway is a clinically effective strategy in treating bladder cancer, including in the NMIBC, BCG-unresponsive setting.

Table 8: American Urology Association (AUA) Risk Stratification for Non-Muscle Invasive Bladder Cancer

Low Risk	Intermediate Risk	High Risk

- Papillary urothelial neoplasm of low malignant potential
- Low grade urothelial carcinoma
  - Ta and
  - □3 cm and
  - Solitary

- Low grade urothelial carcinoma
  - T1 or
  - >3 cm or
  - Multifocal or
  - Recurrence within 1 year

- High grade urothelial carcinoma
  - CIS or
  - T1 or
  - >3 cm or
  - Multifocal

- High grade urothelial carcinoma
  - Ta and
  - □3 cm and
  - Solitary

- Very high risk features (any):
  - BCG unresponsive
  - Variant histologies
  - Lymphovascular invasion
  - Prostatic urethral invasion

* Within each of these risk strata an individual patient may have more or less concerning features that can influence care.

The bladder cancer market was expected to generate $2.3 billion in revenue in 2021 and is expected to grow to $9.3 billion by 2026.

Ongoing and planned investigator-initiated trials will provide data that we can use in our own development of IO102-IO103. See Tables 10 and 11 below for additional details on these trials.

Clinical Development in Neo-Adjuvant / Adjuvant Setting,

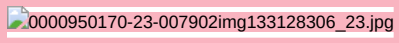
In addition to first-line metastatic cancer indications, we also plan to investigate the dual epitope IO102-IO103 used before or after curatively intended surgery as a neo-adjuvant/adjuvant therapy. We plan to conduct a Phase 2 basket trial, other than the IOB-032 trial which will enable us to investigate multiple solid tumor indications in anti PD-1/PD-L1 naïve settings.

Our planned basket trial will investigate the safety and efficacy of IO102-IO103 in combination with anti-PD 1 in each of the below indications:

- Melanoma
- SCCHN
- Additional indication(s)

We plan to first expand the sample size in Phase 2 and then move into a Phase 3 trial in one or more of these indications if a sufficiently strong efficacy signal is observed and the tolerability data are generally consistent with previous clinical trials.

Figure 18: Schematic Clinical Development Diagram



Additional Trials in Other First-Line Indications and Neo-Adjuvant and Adjuvant Settings

There are multiple potential indication expansion opportunities in various cancer settings with limited anti-PD-1 mAb efficacy or tolerability and toxicity concerns. Both IDO and PD-L1 are highly expressed in numerous other solid tumor indications where anti PD-1-mAb is also approved. Therefore, we believe the potential for the dual epitope IO102-IO103 product candidate in combination with anti PD-1-mAB is significant beyond first-line treatment of advanced melanoma—both as a first-line treatment, but also as a neo-adjuvant (before surgery)/adjuvant (after surgery) therapy. A series of investigator-initiated trials has been completed and others are ongoing that will inform our own development. Safety data from these trials is included in the tables below.

Table 9: Adverse Events Summary of Completed Investigator Initiated Trials

The following table summarizes adverse events reported by the clinical investigators:

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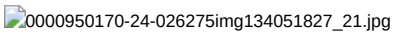

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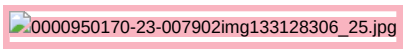

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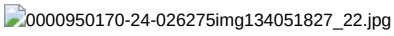
Table 10: Ongoing Investigator Initiated Trials



Additionally, the following table describes currently planned investigator-initiated trials.

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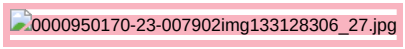
Table 11: Planned Investigator Initiated Trials



The clinical trials listed in Tables Table 10 and 11 above are investigator-initiated trials and accordingly we do not have control over the timing of such trials.

IO102 (IDO)

IO102 is our fully-owned novel product candidate containing a single IDO-derived peptide sequence designed to engage and activate IDO-specific human T cells. This is different from small molecule IDO inhibitors, such as epacadostat, which are designed to block IDO expression on cells. IO102 is the second generation IDO therapy investigated by us. The first IDO therapy we investigated, IO101, is a 9-amino acid peptide investigated in a Phase 1 trial in patients with metastatic NSCLC. The IO101 peptide is an HLA-A2-restricted, IDO-derived CD8+ T cell epitope. IO102 comprises the original CD8+ T cell epitope encoded by IO101 but also contains additional CD8+ T cell epitopes as well as $CD4^{+}$ T cell epitopes.

Clinical trial testing of IO102 in a randomized Phase 1/2 trial in combination with pembrolizumab standard-of-care in first-line treatment of patients with metastatic NSCLC has been completed.

Clinical Development of IO102

As described above, our second generation IDO compound, IO102, is currently being tested in an open-labelled, randomized Phase 1/2 trial in combination with pembrolizumab with or without chemotherapy as first-line treatment for patients with metastatic NSCLC. Continued development of IO102 will be with IO103 and potentially with IO112 and other antigens as part of multiantigen approaches.

IO103 (PD-L1)

IO103 is our fully-owned, novel product candidate containing a single PD-L1-derived peptide designed to engage and activate PD-L1 specific human T cells.

PD-1 and its ligand PD-L1 constitute an important immune regulatory pathway. The interaction between PD-1 and PD-L1 negatively regulates the proliferation and cytokine production of T cells. Accordingly, cancers upregulate PD-L1 to evade the host immune system and PD-L1 expression is correlated with increased tumor aggressiveness and poor prognosis. PD-L1 expression has been reported for both hematological cancer and solid tumors.

IO103 was tested in a single-arm Phase 2 trial assessing IO103 as a monotherapy in patients with Basal Cell Carcinoma (BCC) of the skin.

Clinical Development of IO103

IO103 was investigated in a small, mechanism of action focused Phase 2a trial of 10 patients with resectable BCC on a standalone basis. IO103 has previously been investigated in a first in-human study in patients with multiple myeloma and in smoldering myeloma (Tables 9 and 10 above). The primary objective was to investigate objective and relative (%) reduction of the target lesion as well as the tolerability and immunogenicity after treatment with IO103 in patients with BCC.

Ten patients with resectable BCC were treated with up to nine injections. Adverse events observed during each of the trials were grade 1–2 and most of these grade 1-2 adverse events were injection site reactions. One patient had a history of decreased vision due to wet age-related macular degeneration prior to inclusion in the trial. This adverse event was not deemed related to treatment with IO103.

Table 12: Adverse Events by CTCAE Grade and Frequency

Adverse event	Grade 1, n (%)	Grade 2, n (%)
Injection site reaction	10 (100)	—
Flu-like symptoms after injection	1 (10)	—
Deterioration of vision due to worsening known age-related macular degeneration	—	1 (10)
Traumatic eye injury	—	1 (10)

All patients exhibited peptide specific immune responses in T cells and in skin-infiltrating lymphocytes. IO103's continued development will be exclusively as part of the dual epitope candidate IO102-IO103 and potentially other dual epitope candidates combined with our antigens or multi-antigen developments.

IO112 (Arginase 1)

IO112 is our fully-owned, novel product candidate containing a single Arginase 1-derived peptide designed to engage and activate Arginase 1-specific human T cells. IO112 is designed to target T cells that recognize epitopes derived from Arginase 1, which is an immunoregulatory enzyme highly expressed in difficult-to-treat tumors associated with high levels of MDSCs including colorectal, breast, prostate and pancreatic and ovarian cancers.

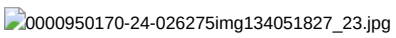
Arginase 1 contributes to immune regulation by catabolizing and limiting the availability of arginine, an essential amino acid for immune effector cell survival and growth. Arginase overproduction by immune suppressive cells like myeloid derived suppressor cells and tolerogenic dendritic cells is a well-documented tumor escape mechanism. Increased levels of arginase have been detected on tumor and immune cells in several solid tumor types.

Preclinical Development

IO112 is designed to selectively engage and activate cancer patients' own T cells to attack Arginase 1-expressing target cells. Upon activation, T cells secrete proinflammatory cytokines such as IFN□ and TNF□, thereby contributing to immune modulation of microenvironment.

Immunotherapeutic activity of murine Arginase 1 peptide therapy (mIO112) has been observed in multiple Arginase 1-expressing tumor models. Arginase 1 treatment resulted in a concomitant reduction of Arginase 1+ cells and an increased influx of T cells into the TME. The treatment approach enhanced the anti-tumor effect of an anti-PD-1 antibody treatment in a colon adenocarcinoma model, MC38.

Figure 19: 13: Arginase 1 Therapy in Mouse Colon Cancer Model



Treatment combining Arginase 1 therapy and aPD-1 treatment results in synergistic response in a mouse colon cancer model, MC38 (A). In this model, mIO112 treatment (and in combination with aPD-1) results in increased influx of immune cells into TME while promoting enrichment of M1 macrophages (B). In another model (fibrosarcoma, MCA205), increased influx of T cells (CD3 staining) and reduction of Arginase 1-expressing cells in the TME was observed in mice treated with Arginase 1 therapy (ovalbumin (OVA) used as irrelevant peptide control) (C).

Clinical Development of IO112

The next indications that we look to explore are difficult to treat cancers, and therefore ARG-1 Arginase 1 was tested in a single-arm first-in-human Phase 1 trial in patients with arginase-positive solid tumors conducted in an investigator-initiated trial at the University of Copenhagen. This was an exploratory safety study to determine if this product can be advanced together with IO102-IO103 or as a component of other multiantigen approaches.

Longer term, we are considering investigating our product candidates in difficult to treat tumors which often express high levels of arginase, such as colorectal, breast, prostate, pancreatic and ovarian cancer. These are all large indications with significant unmet medical need and large commercial potential.

Preclinical Compounds

In addition to IO102, IO103 and IO112, we are evaluating additional potential targets that we believe have potential for use in solid tumors. All our compounds in preclinical development target well-documented immunosuppressive molecules that are known to be overexpressed in the TME across a wide range of tumors. These targets are differentially expressed on tumors compared to normal tissue and cover multiple cancer indications. For example, we are evaluating the potential anti-tumor effect of a novel immune-modulatory cancer therapy using TGF-ß-derived peptides (IO170) in murine tumor models. Transforming growth factor-ß (TGF-ß) is one of the key molecules that contribute to immunosuppression and it is produced in large amounts in the TME by not only cancer cells but also by suppressive and regulatory cells.

Collaborations

Agreements with Herlev University Hospital (Herlev)

Option Agreements with Herlev

We have entered into a number of agreements with Herlev in Denmark granting us options to acquire certain intellectual property rights related to our programs. The primary agreement governing these rights is Framework Assignment Agreement (the Framework Assignment Agreement) that we entered into with Herlev in May 2016. Under the Framework Assignment Agreement, Herlev grants us options to acquire licenses to data and assignments of patent rights in and to certain inventions related to activating or boosting T cells that react towards regulatory immune cells for the treatment and prevention of cancer (the Field) developed by Drs. Mads Hald Andersen and Inge Marie Svane. We have a period of three months after disclosure by Herlev of any applicable invention to exercise our option with respect to such invention in the Field. Upon exercise of any option, we will negotiate in good faith with Herlev regarding the terms of an assignment agreement for such invention in the Field. If we are unable to agree to terms of such assignment within six months of exercise of the option, Herlev will have no further obligation to continue negotiations with respect to such invention.

The Framework Assignment Agreement will continue until termination by either party. Under the Framework Assignment Agreement, either party may terminate the agreement (1) for convenience, upon six months' prior written notice or (2) for the other party's uncured material breach. Termination of the Framework Assignment Agreement for any reason will not affect any assignment agreement entered into prior to such termination.

We have exercised our options granted under the Framework Assignment Agreement, and other option agreements with Herlev, and obtained assignments and licenses related to certain inventions, including inventions related to our lead product candidates, IO102, IO103, IO112 and IO112.IO170.

Assignment Agreements with Herlev

In January 2015, January 2017 and December 2018, respectively, we exercised options granted by Herlev, and acquired Herlev's rights and title in and to the patent applications related to Indoleamine 2, 3-dioxygenase based immunotherapies, PD-L1-based immunotherapies and PD-LI peptides for use in cancer vaccines, such as our T-win T-win® product candidates, and Arginase specific T cells. In connection with such acquisitions, Herlev has also granted us non-exclusive licenses under any clinical data related to such patent rights arising at Herlev for the purpose of developing and commercializing the inventions and patent rights. The agreements pursuant to which we have obtained these rights and licenses (the Assignment Agreements) are non-terminable.

Pursuant to the Assignment Agreements and other similar agreements with Herlev, we have paid and are obligated to pay future contingent payments and royalties, including upon achieving potential regulatory milestones and low single digit royalties on net sales from sales of products incorporating the acquired patent rights and other revenues arising from the acquired patent rights. Upon the occurrence of a change of control, stock or asset sale or IPO, certain outstanding milestone payments under such agreements

became due immediately in the aggregate of approximately DKK 13.2 million (which is approximately $1.9 million based on the exchange rate of DKK 6.95 6.75 to one U.S. dollar on December 31, 2022 December 31, 2023). This was triggered by our IPO in November 2021, and has subsequently been paid. We have the right to buy-out all remaining payment obligations under the Assignment Agreement at any time by paying DKK 20 million (for each of the PD-L1 technology and IDO technology) or DKK 10 million (for the Arginase technology) to Herlev.

Under the Assignment Agreements, we control all rights to the covered patents and, with respect to the PD-L1 and Arginase technology, are required to use our best reasonable efforts to manage, prosecute, maintain and enforce, and we are not permitted to abandon, the acquired patent rights certain markets, including Denmark and certain other EU countries, the UK, the US, Canada, Japan and China.

Research Agreements with Herlev

In connection with the Framework Assignment Agreement, we entered into a Framework Cooperation Agreement (the Framework Cooperation Agreement) with Herlev in January 2017, and as amended in December 2018, in which we agreed to cooperate with Herlev, either through co-financed research or sponsored research, for certain agreed-upon research programs to develop therapies aimed at activating or boosting T cells that react towards regulatory immune cells for the treatment and prevention of cancer (the Field). Pursuant to the Framework Cooperation Agreement, we will have the option to acquire all intellectual property rights in inventions developed in the course of any research program, under the terms of the Framework

Assignment Agreement. The Framework Cooperation Agreement does not have a set expiration date, but may be terminated by either party (1) for convenience, upon six months' prior written notice, or (2) for the other party's uncured material breach.

Each research program under the Framework Cooperation Agreement will be conducted under a separate cooperation agreement (each, a Cooperation Agreement). We are currently engaged in six co-financed or sponsored research programs in the Field, each under a separate Cooperation Agreement. Each Cooperation Agreement will continue until the completion of the applicable research program, and either party may terminate such Cooperation Agreement, (1) for convenience, upon three months' prior written notice, or (2) for the other party's uncured material breach.

Additionally, we have entered into a separate agreement with Herlev pursuant to which we were obligated to pay a cash fee in the amount of DKK 5.0 million (which is approximately $0.7 million based on the exchange rate of DKK 6.95 6.75 to one U.S. dollar on December 31, 2022 December 31, 2023) upon the occurrence of a change of control, stock or asset sale or IPO. This was triggered by our IPO in November 2021, and has subsequently been paid.

Clinical Trial Collaboration and Supply Agreements with MSD International GmbH

November 2022 Agreement

In November 2022, we entered into a clinical collaboration with MSDIG, an affiliate of Merck, and MSD International Business GmbH (MSDIB), another affiliate of Merck (collectively, MSD) to evaluate IO102-IO103 in combination with KEYTRUDA® as a neo-adjuvant/adjuvant therapy for patients with metastatic melanoma and SSCHN. Under the terms of the collaboration with MSD, we will conduct an international Phase 2 study to evaluate a combination therapy of IO102-IO103 and KEYTRUDA®. We will sponsor the clinical trials and MSD will provide KEYTRUDA® to be used in the clinical trials free of charge. We and MSD will be responsible for our own internal costs and expenses to support the study and we shall bear all other costs associated with conducting the study, including costs of providing IO102-IO103 for use in the study. The rights to the data from the clinical trials will be shared by us and MSD and we will maintain global commercial rights to IO102-IO103.

December 2021 Agreement

In December 2021, we entered into a Clinical Trial Collaboration and Supply Agreement (the CTCSA) with MSD. Under the CTCSA, we will collaborate with MSD regarding the conduct of our international Phase II trial for our compounds, IO102 and IO103, in combination with MSD's pembrolizumab, a humanized anti-human PD-1 monoclonal antibody, for the treatment of metastatic NSCLC, SCCHN or UBC (the Trial). Under the CTCSA, we will act as the sponsor of the Trial at our cost, and MSD will supply pembrolizumab for use in the Trial. Neither party will have any obligation to reimburse costs incurred by the other party in connection with the Trial or the supply of pembrolizumab, except upon certain breach or early termination events.

The CTCSA will remain in effect until we provide MSD with top-line results and a final report of the results, promptly after the Trial is completed, unless terminated earlier by either party for the other party's material breach if such party fails to cure such breach within the specified cure period, or upon certain other occurrences specified in the CTCSA.

September 2021 Agreement

In September 2021, we entered into an additional Clinical Trial Collaboration and Supply Agreement (the MSD Agreement) with MSDIG, and MSDIB to collaborate regarding the conduct of our international Phase 3 trial for the Company's compounds, IO102-IO103, in combination with MSD's anti-PD-1 therapy, Keytruda, for the treatment of advanced melanoma (the MSD Study). Each party is required to use commercially reasonable efforts to supply its compound, at its own cost, for use in the MSD Study. Under the MSD Agreement, we will act as the sponsor of the MSD Study at our cost (except for the cost of the supply of Keytruda from MSD and certain other internal costs incurred by MSD in conducting the MSD Study).

Under the MSD Agreement, all clinical data besides the data arising from the arm of the MSD Study involving only Keytruda will be jointly owned by us and MSD. All inventions relating to the combined use of IO102-IO103 and Keytruda arising from the MSD Study will also be jointly owned by us and MSD. We do not have the right under these jointly owned inventions to research, develop or commercialize any PD-1 antagonist and MSD does not have the right under the jointly owned inventions to research, develop or commercialize any peptide vaccine, such as our T-win T-win® product candidates, containing an IDO- or PD-L1-derived peptide. We have the first right to enforce such jointly owned patents. We will own all rights in any inventions or improvements arising from the MSD Study relating solely to or solely covering IO102-IO103 or any a compound that is a peptide vaccine, such as our T-win product candidates, containing an IDO- or PD-L1-derived peptide and MSD will own all rights in any inventions or improvements arising from the MSD Study relating solely to or solely covering Keytruda

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or any PD-1 antagonist. The parties agreed that positive clinical data from the MSD Study may be used to obtain label changes for each party's respective compounds to add an indication for combination therapy.

Under the MSD Agreement, MSD has a limited time right of first negotiation to enter into a definitive agreement with us to develop and commercialize IO102 or IO103. We will be free to negotiate with third parties regarding rights to IO102 or IO103 if MSD does not exercise its right of first negotiation within the exercise period or if the parties are not able to enter into an agreement during the negotiation period.

The MSD Agreement will remain in effect until delivery of the MSD Study's final analysis by us to MSD, unless terminated earlier by either party: (1) for the other party's material breach if such party fails to cure such breach within the specified cure period; (2) upon a good faith determination by the terminating party that there is a patient safety concern regarding the MSD Study; (3) if any regulatory authority takes any action that prevents the terminating party from supplying its compound for the MSD Study; (4) if the terminating party determines to withdraw any regulatory approval for its compound or discontinue development of its compound; or (5) for the other party's failure to comply with its anti-corruption obligations. Upon termination by MSD due to our material breach or our failure to perform any obligations related to anti-corruption laws, we are required to reimburse MSD for the direct and indirect manufacturing costs incurred by MSD in delivering its compound for the MSD Study.

February 2018 Agreement

In February 2018, we entered into a Clinical Trial Collaboration and Supply Agreement (the Merck Collaboration Agreement) with MSDIG, an affiliate of Merck, to collaborate regarding the conduct of the Company's international Phase 1/2 trial for the Company's compound, IO102, in combination with MSDIG's anti-PD-1 therapy, Keytruda (pembrolizumab), for the treatment of non-small cell lung cancer (the Study). Each party is required to use commercially reasonable efforts to supply its compound, at its own cost, for use in the Study. Under the Merck Collaboration Agreement, we will act as the sponsor of the Study at our cost (except for the cost of the supply of Keytruda from MSDIG and certain other internal costs incurred by MSDIG in conducting the Study).

Under the Merck Collaboration Agreement, all clinical data arising from the Study and all inventions relating to the combined use of IO102 and Keytruda arising from the Study will be jointly owned by us and MSDIG. We do not have the right under these jointly owned inventions to commercialize any PD-1 antagonist and MSDIG does not have the right under the jointly owned inventions to commercialize any peptide vaccine, such as our T-win T-win® product candidates, containing an IDO-derived peptide. The parties are jointly responsible for prosecuting and maintaining the joint patents, and we have the first right to enforce the joint patents. We will own all rights in any inventions or improvements arising from the Study relating solely to or solely covering IO102 or any a compound that is a peptide vaccine, such as our T-win product candidates, containing an IDO-derived peptide and MSDIG will own all rights in any inventions or improvements arising from the Study relating solely to or solely covering Keytruda or any PD-1 antagonist.

During the term of the Merck Collaboration Agreement and for six months thereafter, each party has the option to propose an amendment to the Merck Collaboration Agreement or a new agreement for a registration study for the combination of IO102 and Keytruda for the treatment of non-small cell lung cancer. If either party makes such a proposal, the other party is obligated to negotiate in good faith the terms of such an amendment or agreement. In addition, we are obligated to offer MSDIG the option of participating in a registration study for the treatment of non-small cell lung cancer using IO102 in combination with Keytruda before we enter into an agreement with any third party to conduct a registration study for non-small cell lung cancer for IO102 in combination with a PD-1 antagonist.

The Merck Collaboration Agreement will remain in effect until delivery of the final study report for the Study by the Company, unless terminated by either party: (1) for the other party's material breach if such party fails to cure such breach within the specified cure period; (2) upon a good faith determination by the terminating party that there is a

patient safety concern regarding the Study; (3) if any regulatory authority takes any action that prevents the terminating party from supplying its compound for the Study; (4) if the terminating party determines to withdraw any regulatory approval for its compound or discontinue development of its compound; or (5) for the other party's failure to comply with its anti-corruption obligations. Upon termination by MSDIG due to our material breach or our failure to perform any obligations related to anti-corruption laws, we are required to reimburse MSDIG for the direct and indirect manufacturing costs incurred by MSDIG in delivering its compound for the Study.

Clinical Trial Research Agreement with Cliniques Universitaires Saint-Luc

In November 2019, we entered into a Clinical Trial Research Agreement (the Clinical Trial Agreement) with Cliniques Universitaires Saint-Luc (Saint-Luc) in Belgium in order to conduct an investigator-initiated study regarding the activity and safety of peptide-based immunotherapy in the pre-operative setting for patients with squamous-cell carcinoma of the head and neck (the Saint-Luc Study). The Saint-Luc Study is designed as an umbrella trial enabling the testing of multiple of our compounds, including IO102, IO103 and IO112, after initial testing of IO102 in a monotherapy setting. We are responsible for payment of costs associated with the Saint-Luc Study in accordance with an agreed-upon budget.

Saint-Luc is the sponsor of the Saint-Luc Study and owns all inventions arising from, and data and results generated in, the Saint-Luc Study, and has agreed to grant us an exclusive license to all data and results generated during the Saint-Luc Study. In addition, we have the exclusive right to evaluate, prepare, file, prosecute and maintain patent rights related to any inventions, and we will own all such patented inventions. Saint-Luc is required to take all actions necessary to assign rights in any such patents to us.

The Clinical Trial Agreement will continue for the term of the Saint-Luc Study, unless terminated earlier by either party for convenience or the other party's material breach, subject to applicable notice and cure periods. In addition, we have the right to terminate the Clinical Trial Agreement for various reasons related to the conduct of the Saint-Luc Study, as specified in the Clinical Trial Agreement.

Competition

Our industry is intensely competitive and subject to rapid and significant technological change. While we believe that our knowledge, experience and scientific resources provide us with competitive advantages, we face substantial competition from major pharmaceutical companies and biotechnology companies, academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and established collaborative arrangements for the research, development, manufacturing and commercialization of cancer immunotherapies. Many of our competitors have significantly greater financial, technical and human resources. Smaller and early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. As a result, our competitors may discover, develop, license or commercialize products before or more successfully than we do.

We face competition with respect to our current product candidates, and will face competition with respect to future product candidates, from segments of the pharmaceutical, biotechnology and other related markets that pursue immune-oncology treatments.

Specifically, there are many companies that commercialize or are developing immuno-oncology treatments for cancer including large pharmaceutical and biotechnology companies such as Amgen, AstraZeneca, BMS, Merck, Novartis, Pfizer, Moderna, Regeneron, Roche, and Roche's subsidiary Genentech.

In melanoma specifically, the dominant market players are nivolumab, marketed by BMS and Ono, combination of nivolumab & ipilimumab, marketed by BMS and Ono, combination of nivolumab and relatlimab (LAG-3 blocking antibody) marketed by BMS and pembrolizumab, marketed by Merck. We are also aware of several companies testing their compounds in combination with nivolumab or pembrolizumab. In mid stage development there is Moderna and Merck with an investigational personalized mRNA cancer vaccine, in combination with pembrolizumab. In earlier stage development there are also BioNTech with NEO-PV-01 and Karyopharm with selinexor.

We are not aware of any human peptides targeting the TME that are currently in late stage development for melanoma, NSCLC, bladder cancer or other solid tumors.

Our competitors may obtain regulatory approval of their products more rapidly than we may or may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize our product candidates. Our competitors may also develop drugs that are more effective, more convenient, more widely used and less costly or have a better safety profile than our products and these competitors may also be more successful than us in manufacturing and marketing their products. Our competitors will may also compete with us in recruiting and retaining qualified scientific, management and commercial personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Furthermore, we also face competition more broadly across the market for cost-effective and reimbursable cancer treatments. The most common methods of treating patients with cancer are surgery, radiation and drug therapy, including chemotherapy, hormone therapy and targeted drug therapy, or a combination of such methods. There are a variety of available

drug therapies marketed for cancer. In many cases, these drugs are administered in combination to enhance efficacy. While our product candidates, if any are approved, may compete with these existing drug and other therapies, to the extent they are ultimately used in combination with or as an adjunct to these therapies, our product candidates may not be competitive with them.

Some of these our competitors' drugs are may be branded and subject to patent protection, and others are available on a generic basis. Insurers and other third-party payors may also encourage the use of generic products or specific branded products. We expect that if our product candidates are approved, they will be priced at a significant premium over competitive generic, including branded generic, products. As a result, obtaining market acceptance of, and gaining a significant share of the market for, any of the product candidates that we successfully introduce to the market may pose challenges. In addition, many companies are developing new therapeutics, and we cannot predict what the standard of care will be as our product candidates progress through clinical development.

The acquisition or licensing of pharmaceutical products is also very competitive. If we seek to acquire or license products, we will may face substantial competition from a number of more established companies, some of which have acknowledged strategies to license or acquire products, and many of which are bigger than us and have more institutional experience and greater cash flows than we have. These more established companies may have competitive advantages over us, as may other emerging companies taking similar or different approaches to product licenses and/or acquisitions. In addition, a number of established research-based pharmaceutical and biotechnology companies may acquire products in late stages of development to augment their internal product lines, which may provide those companies with an even greater competitive advantage.

Manufacturing and Supply

Our compounds are linear peptides formulated as lyophilized powders to ensure long-term shelf-life and reconstituted with water for injection and emulsified with adjuvant prior to subcutaneously administration. The manufacturing process of our compounds has multiple advantages over other immuno-oncology compounds. The manufacturing process is based on a well-understood process solid state peptide synthesis and data has proven our compounds to be stable for a long period at easy-to-administer temperatures. The cost of goods sold for both trials and commercial use is expected to be relatively low.

We currently do not own or operate any manufacturing facilities nor do we have any plans to do so in the foreseeable future. We rely on, and expect to continue to rely on, third-party contract development and manufacturing organizations to continue the development and the optimization of our product candidates and to ensure that suitable manufacturing processes are in place for both present scales and future commercial scales of production of our product candidates. This ensures that all products manufactured under our responsibility are done in accordance with relevant regulatory requirements and approval and includes those product materials intended for use in our preclinical and clinical testing, as well as commercial manufacture.

We believe that our strategy and workforce allow us to maintain an efficient infrastructure and ensure we do not need to invest in expensive manufacturing facilities and equipment. The Our personnel within the organization enable us to focus our expertise and resources on the development of our product candidates and the management of third parties.

To date, we have obtained active pharmaceutical ingredients (API) from qualified facilities with the relevant expertise to manufacture our drug substances. Likewise, suitably qualified facilities with relevant experience have been used to manufacture our drug products. All third parties are assessed under our quality system and appropriate quality agreements to ensure compliance are in place. We maintain agreements with our manufacturers and ensure that confidentiality and intellectual property provisions to protect our proprietary rights related to our product candidates are in place.

We are in the process of further optimizing and developing our supply chain for each of our product candidates to ensure continuity of supply and capacity for intended commercial scales.

Commercialization

We hold worldwide development and commercial rights to our pipeline of immuno-oncology therapeutic cancer vaccine programs, and we intend to commercialize our product candidates, if approved, in key geographies. We do not currently have our own marketing, sales, or distribution capabilities. To commercialize IO102-IO103, if approved for commercial sale, we would have to develop a establish marketing and sales and marketing infrastructure.capabilities internally or through collaborators.

Subject to receiving marketing approvals, we plan to commence commercialization activities by building a focused marketing and sales and organization. The marketing organization to sell our products. We believe that such an would be responsible for creating and implementing marketing strategies and tactics. The sales organization will would be able to address responsible for overseeing and supporting the community of oncologists who are the key specialists in treating the patient populations for which our product candidates are being

developed. sales force. We may selectively enter into distribution, and marketing or other marketing commercial arrangements with third parties for any of our product candidates that obtain marketing approval if we believe these collaborations could maximize the value of our product candidates.

We also plan to build a marketing and sales management organization to create and implement marketing strategies for any products that we market through our own sales organization and to oversee and support our sales force. The responsibilities of the marketing organization would include developing educational initiatives with respect to approved products and establishing relationships with researchers and practitioners in relevant fields of medicine.

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 assigned from third parties. We own the issued patents and patent applications relating to all compounds in our portfolio. Our policy includes seeking to protect our proprietary position by, among other methods, filing patent applications, in the United States and in jurisdictions outside of the United States, directed to at 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, continued innovation, and in-licensing opportunities to develop, strengthen and maintain our proprietary position in the field of immunotherapy. We also plan to rely on data exclusivity, market exclusivity, and supplementary protection certificates / patent term extensions (SPC/PTE) when available. Our commercial success will depend in part on our ability to obtain and maintain patent and other proprietary protection for our technology, inventions, and improvements; to preserve the confidentiality of our trade secrets and know-how; to obtain and maintain licenses to use intellectual property owned by third parties; to defend and enforce our proprietary rights, including any patents that we may own in the future; and to operate without infringing, misappropriating or otherwise violating the valid and enforceable patents and other proprietary rights of third parties. For more information, please see “Risk Factors—Risks Related to Intellectual Property.”

Patents

Our patent portfolio is currently comprised of 17 separate patent families. These are numbered as Families 1 to 17 and are discussed in more detail below. The families are divided into groups based on therapeutic targets. Some of the families span more than one target, particularly with respect to the patents for our lead compounds directed to the target IDO (compound IO102) and target PD-L1 (compound IO103).

- **IO102 (IDO)**: We own five patent families covering compositions of matter and methods of treatment related to IO102, which were filed between 2009-2023. 2009 and 2023. These are Families 1, 2, 3, 13 and 15.
  - Family 1 is based on an international (PCT) application filed 17 April 2009. April 17, 2009. Patents granted from this family will expire 17 April 2029 April 17 based on a normal 20 year term. In the United States, a granted patent covering IO102 as a composition of matter will expire 7 October 2029 October 7, 20 to a patent term adjustment of 173 days. A separate granted patent in the United States covers methods of treatment using IO102 and will expire 2 2029 May 28, 2029 due to a patent term adjustment of 41 days. A separate pending granted patent in the United States application covers nucleotides en IO102 and has received a notice of allowance. will expire April 17, 2029 (no patent term adjustment). A further separate pending United States application filed shortly to pursue alternative subject matter. covers methods of treatment using nucleotides encoding IO102. In other jurisdictions it is not typically nec to present claims to compositions of matter separately from methods of treatment and thus both types of claim appear in the same patent. The family in granted patents in Europe, Hong Kong, China, Japan, Canada, Australia, Israel, New Zealand and South Africa, each of which has claims covering IO10 compositions of matter and the local equivalent of methods of treatment using IO102. Grant of a corresponding application in Hong Kong is imminent. E these patents has the normal 20 year term expiring 17 April 2029. April 17, 2029. The family also includes a pending applications in application at the States and European Patent Office (EPO);
  - Family 2 is based on a PCT application filed 3 March 2017. March 3, 2017. Patents granted from this family will expire 3 March 2037 March 3, 2037 base normal 20 year term. A granted patent in Europe covers a combination of IO102, IO103 and an anti-PD1 antibody for use in a method for preventing or t cancer. A pending application in Japan covers the same subject matter and has received a notice of allowance. Separate pending applications in Euro Japan will pursue claims which cover administration of IO102 + anti-PD-1 in a separate composition to IO103. The family also includes a p applications application in the United States Europe with claims covering a method of treating a PD-L1 expressing cancer by administering IO103 + anti-PD Japan. Claims are directed combined uses of IO102, IO103 and a checkpoint inhibitor; an adjuvant;

  - Family 3 is based on a PCT application filed 23 April 2018. April 23, 2018. Patents granted from this family will expire 23 April 2038 April 23, 2038 base normal 20 year term. The family includes pending applications in the United States, Europe, Japan and China. Claims are directed to combined uses of IO103 and a specific category of therapeutic antibody, *i.e.* i.e. those which operate via antibody-dependent cellular cytotoxicity (ADCC) mechanisms of actio

- Family 13 is based on a PCT application filed 31 August 2021. August 31, 2021. Patents granted from this family will expire August 31, 2041 based on a 20 year term. The family includes pending applications in the United States, Europe, China, Japan, Republic of Korea, Singapore, Canada, Australia and Claims are directed to combined uses of IO102, IO103 and anti-PD1 antibody; and
- Family 15 is based on a PCT application filed February 23, 2023. National phase applications in other jurisdictions will be filed in due course. Patents grante this family will expire 31 August 2041 based on a normal 20 year term. February 23, 2043. Claims are directed to combined uses of IO102, IO103 and ar antibody. mRNAs encoding all existing candidates in the IO Biotech portfolio, including IO102.

- **IO103 (PD-L1)**: We own six five patent families covering compositions of matter and methods of treatment related to IO103, which were filed between 2012-2023. 2012 through 2023. These are Families 2, 3, 13 and 15 listed above, plus Families Family 4 and 5 set out below. Family 5 covers alternative PD-L1 compound IO104.1.
  - Family 4 is based on a PCT application filed 17 October 2012. October 17, 2012. Patents granted from this family will expire 17 October 2032 October 17 based on a normal 20 year term. In the United States, a granted patent covering IO103 as a composition of matter and methods of treatment using IO1 expire 11 May 2033 May 11, 2033 due to a patent term adjustment of 206 days. The family includes granted patents in Europe, China, Japan, Brazil and C each of which has claims covering IO103 as a composition of matter and the local equivalent of methods of treatment using IO103. The family also in pending applications in the EPO Europe, Hong Kong and China; and
  - Family 5 is based on a PCT application filed 20 June 2017. June 20, 2017. Patents granted from this family will expire 20 June 2037 June 20, 2037 base normal 20 year term. A granted patent in China covers alternative PD-L1 compound IO104.1 as a composition of matter and methods of treatment using IO We anticipate calculating patent term adjustment in the near future. The family includes pending applications in the United States, Europe, Japan and Claims are directed to Japan. IO103 and an alternative compound IO104.1, and uses thereof. The is also disclosed in the application, but the data application is primarily concerned with IO104.1, and so as such prosecution will focus is focused on securing claims to this compound first. compound.

- **IO112 (Arginase 1)**: We own three patent families covering compositions of matter related to IO 112, IO112, which were filed between 2017-2023. 2017 through 2023. These are Family 15 as listed above, plus Families 6 and 7set 7 set out below.
  - Family 6 is based on a PCT application filed 6 October 2017. October 6, 2017. Patents granted from this family will expire 6 October 2037 October 6, 2037 on a normal 20 year term. In the United States, there is a granted patent with this expiry date which covers IO112 as a composition of matter and meth treatment using IO112. A separate pending application in the United States covers methods of preparing a pharmaceutical composition comprising IO112 a received a notice of allowance. A granted patent in Japan covers IO112 as a composition of matter, as well as nucleotides encoding IO112 and meth treatment using the same. A pending application in Europe covers the same and has received a notice of allowance. The family also includes pending appli in the United States, the EPO, Hong Kong, China, Japan, Australia, Canada, Israel, Republic of Korea, Mexico, and Singapore. Mexico. Grant is immi Japan. Singapore and Israel. This family is also relevant to Arginase 2; and
  - Family 7 is based on a PCT application filed 24 September 2019. September 24, 2019. Patents granted from this family will expire 24 September 2039 Sept 24, 2039 based on a normal 20 year term. The family includes pending applications in the United States, the EPO, China, Japan, Australia, Canada, Republic of Korea, Mexico, and Singapore. The claims are directed specifically to IO112, and uses thereof.

- We have additional patent families relevant to the following targets:
  - **TDO**: We own one patent family based on a PCT application filed 15 September 2015. September 15, 2015. This is Family 8. Patents granted from this family will expire 15 September 2035 September 15, 2035 based on a normal 20 year term. In the United States, a granted patent covering TDO candidate peptides and methods of treatment using the same will expire March 1, 2036 due to a patent term. adjustment of 168 days. A separate granted patent in the United States covers nucleic acids encoding the TDO candidate peptides and will expire February 21, 2037 due to a patent term adjustment of 525 days. The family includes granted patents in the United States, Europe, China, Japan, Australia, Canada, Israel and South Africa. The family also includes applications a pending application in the United States, EPO and Canada. Europe which will pursue alternative claim scope, including nucleic acids encoding TDO candidate peptides. Grant is imminent in Canada; New Zealand. Family 15 listed above is also relevant;

- **PD-L2**: We own one patent family based on a PCT application filed 13 October 2017. October 13, 2017. This is Family 9. Patents granted from this family will expire 13 October 2037 October 13, 2037 based on a normal 20 year term.term. The family includes a granted patent patents in the United States. States and Japan. The family also includes pending applications in the United States, China, EPO, and Hong Kong, and Japan. Kong. Claims are directed to target candidates, and uses thereof; thereof. Family 15 listed above is also relevant;
- **CCL22**: We own one patent family based on a PCT application filed 16 September 2016. September 16, 2016. This is Family 10. Patents granted from

this family will expire 16 September 2036 September 16, 2036 based on a normal 20 year term. The family includes granted patents in the United States, China, Japan, Israel and Australia. The family also includes pending applications in the United States, China, EPO, Canada, Hong Kong, New Zealand, and South Africa. Claims are directed to target candidates, and uses thereof; thereof. Family 15 listed above is also relevant;

- **Arginase 2**: We own three patent families relevant to this target. The first is Family 6 as listed under IO112 (Arginase 1) above. The second is Family 11, based on a PCT application filed 14 November 2019. November 14, 2019. Patents granted from this family will expire 14 November 2039 November 14, 2039 based on a normal 20 year term The family includes

pending applications in the United States, China, EPO, Japan, Australia, Canada, Israel, Republic of Korea, and Singapore. Claims are directed to candidates, and uses thereof. The third family is Family 14, based on two first filings made in the United Kingdom on 24 February 2022 February 24, 2022 a September 2022. September 13, 2022. A PCT application will be was filed 24 February 2023. February 24, 2023. National phase applications in other jurisc will be filed in due course. Patents granted from this family will expire 24 February 2043 February 24, 2043 based on a normal 20 year term. Claims are dire alternative target candidates, and uses thereof; thereof. Family 15 listed above is also relevant; and

- **TGFbeta TGFβ**: We own three patent families relevant to this target. The first is Family 12, based on a PCT application filed 4 June 2020. June 4, 2020. Patents granted from this family will expire 4 June 2040 June 4, 2040 based on a normal 20 year term. National phase The family includes pending applications in other jurisdictions will be filed in due course. the United States, China, Hong Kong, EPO, Japan, Australia, Canada, Israel, Republic of Korea, Mexico, and Singapore. Claims are directed to target candidates, and uses thereof. The second is Family 16, based on a first filing made in the United Kingdom on 4 November 2022. A PCT application will be filed 4 November 2023. November 3, 2023. National phase applications in other jurisdictions will be filed in due course. Patents granted from this family will expire 4 November 2043 3 November 4, 2043 based on a normal 20 year term. Claims are directed to alternative target candidates, and uses thereof. The third is Family 17, based on a first filing made in the United Kingdom on 28 October 2022. A PCT application will be filed 28 October 2023. October 27, 2023. National phase applications in other jurisdictions will be filed in due course. Patents granted from this family will expire 28 October 2043 October 27, 2043 based on a normal 20 year term. Claims are directed to combined uses of TGFbeta TGFβ target candidates with immune checkpoint inhibitors such as anti-PD1 antibody, as well as methods of predicting responsiveness to anti-PD1 treatment based on immune responses to TGFbeta. TGFβ. Family 15 listed above is also relevant.

Upon receipt of marketing approvals in each country, we will file applications for supplementary protection certificates/patent term extensions (SPC/PTE) as appropriate. These will provide up to an additional 5 years term of protection with respect to each extended patent, although there is no guarantee that we will be able to obtain such SPC/PTE. For more information, please see “Risk Factors— If we do not obtain patent term extension in the United States under the Hatch-Waxman Act and in foreign countries under similar legislation, thereby potentially extending the term of marketing exclusivity for our product candidates, our business may be harmed.”

Trademark

We hold the trademark T-win T-win® in the European Union (Registered no. 017871048), the United States (Registered no. 5754675), China (Registered no. 33152486), Japan (Registered no. 6107125), and the United Kingdom (Registered no. 00917871048). The trademark of T-win is registered in class 5 (including pharmaceuticals and other preparations for medical purposes) and class 42 (including scientific and/or medical research services).

Government Regulation

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, tracking, record keeping, approval, advertising, promotion, marketing, post-approval monitoring and post-approval reporting of biological products such as those we are developing. We, along with our vendors, collaboration partners, contract research organizations (CROs) CROs and CMOs, will be required to navigate the various preclinical, clinical, manufacturing and commercial approval requirements of the governing regulatory agencies of the countries in which we wish to conduct studies or seek approval of our product candidates. The process of obtaining regulatory approvals of biological products and ensuring subsequent compliance with appropriate federal, state, local, and foreign statutes and regulations requires the expenditure of substantial time and financial resources.

In the United States, where we are initially focusing our product development, the FDA regulates biologics under the Federal Food, Drugs, and Cosmetics Act, as amended (FDCA) and the Public Health Service Act, as amended (PHSA) and their implementing regulations. Biologics are also subject to other federal, state and local statutes and regulations. Our product candidates are early-stage and have not been approved by the FDA for marketing in the United States.

Our product candidates must be approved for therapeutic indications by the FDA through a BLA before they may be marketed in the United States. The process generally involves the following:

- completion of extensive preclinical studies in accordance with applicable regulations, including studies conducted in accordance with GLP requirements;

- submission to the FDA of an IND, which must become effective before clinical trials to be conducted in the U.S. may begin and must be updated annually or significant changes are made;

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- approval by an IRB or independent ethics committee at each clinical trial site before each trial may be initiated;
- performance of adequate and well-controlled clinical trials in accordance with GCP requirements and other clinical trial-related regulations to establish the safe efficacy of the investigational biologic for each proposed indication;
- preparation and submission to the FDA of a BLA, after completion of all pivotal trials;
- payment of user fees for FDA review of the BLA;
- potential review of the product application by an FDA advisory committee, where appropriate and if applicable;
- a determination by the FDA within 60 days of its receipt of a BLA to file the application for review;
- satisfactory completion of an FDA advisory committee review, if applicable;
- satisfactory completion of one or more FDA pre-approval inspections of the manufacturing facility or facilities where the biologic will be produced to assess comp with cGMP to assure that the facilities, methods, and controls are adequate to preserve the product's identity and continued safety, purity, and potency;
- potential FDA audit of the preclinical and clinical trial sites that generated the data in support of the BLA;
- FDA review and approval of the BLA, including consideration of the views of any FDA advisory committee, prior to any commercial marketing or sale of the product United States; and
- compliance with any post-approval commitments and / or requirements, including the potential requirement to implement a Risk Evaluation and Mitigation St (REMS) or to conduct a post-approval study.

Nonclinical and Clinical Trials

Nonclinical Trials

Before testing any biologic product in humans, the product candidate must undergo rigorous nonclinical testing *in vitro and in vivo*. Such nonclinical in vitro and in vivo animal studies assess safety and in some cases to establish the rationale for therapeutic use. The conduct of nonclinical studies is subject to federal and state regulations and requirements, including GLP requirements for safety and toxicology studies. The results of the nonclinical studies, together with manufacturing information, a proposed clinical trial protocol, and analytical data must be submitted to the FDA as part of an IND prior to the start of clinical studies in humans. However, some long-term nonclinical testing may continue after the IND is submitted.

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Clinical Trials

Clinical trials to evaluate therapeutic indications to support BLAs for marketing approval are typically conducted in three sequential phases, which may overlap.

- Phase 1—Phase 1 clinical trials involve initial introduction of the investigational product into healthy human volunteers or patients with the target disease or cor These studies are typically designed to test the safety, dosage tolerance, absorption, metabolism, distribution, and excretion of the investigational product in hu evaluate the side effects associated with increasing doses, and, if possible, to gain early evidence of effectiveness;
- Phase 2—Phase 2 clinical trials typically involve administration of the investigational product to a limited patient population with a specified disease or condi evaluate the preliminary efficacy, optimal dosages and dosing schedule and to identify possible adverse side effects and safety risks. Phase 1 trials are som combined with Phase 2 trials. These trials are known as Phase 1/2 trials. Generally, a Phase 1/2 trial is conducted as a single trial that has the characteristics of Phase 1 trial (as described above) and a Phase 2 trial. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more exp Phase 3 clinical trials. Phase 2 trials may be conducted as basket trials where a single investigational drug or drug combination is studied across multiple populations defined by disease stage, histology, number of prior therapies, genetic or other biomarkers, or demographic characteristics; and
- Phase 3—Phase 3 clinical trials typically involve administration of the investigational product to an expanded patient population to further evaluate dosage, to p statistically significant evidence of clinical efficacy and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical tri intended to establish the overall risk/benefit ratio of the investigational product and to provide an adequate basis for approval. Accordingly, these are generally kno registrational trials. Generally, two adequate and well-controlled Phase 3 clinical trials are required by the FDA for approval of a BLA.

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Post-approval trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication and are commonly intended to generate additional information regarding risks, benefits, and optimal use of the

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

Investigational New Drug — Authorization to Conduct Clinical Trials in US

An IND is a request for authorization from the FDA to administer an investigational biologic product to humans and to ship such products in interstate commerce for use in investigational clinical trials. INDs must become effective before clinical trials in the U.S. may begin. The central focus of an IND submission is on the general investigational plan and the protocol(s) for clinical studies. The IND also includes results of animal and in vitro studies assessing the toxicology, carcinogenicity, formulation, pharmacokinetics, pharmacology, and pharmacodynamic characteristics of the product; chemistry, manufacturing, and controls information; any available human data or literature to support the use of the investigational product; and a proposed clinical trial protocol.

The IND automatically becomes effective 30 days after receipt of the submission by the FDA, unless the FDA, within the 30-day time period, raises concerns or questions about the conduct of the clinical trial, including concerns that human research subjects will be exposed to unreasonable health risks, and imposes a clinical hold. In such a case, the IND sponsor must resolve any outstanding concerns before the clinical trial can begin. Accordingly, submission of an IND may or may not result in FDA authorization to begin a trial. A separate submission to an existing IND must also be made for each successive clinical trial conducted during product development of a product candidate, and the FDA must grant permission, either explicitly or implicitly by not objecting, before each clinical trial can begin.

Clinical trials involve the administration of the product candidate to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control in accordance with GCP requirements, which include the requirements 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 clinical trial, dosing procedures, subject selection, and exclusion criteria, and the parameters and criteria to be used in monitoring safety and evaluating effectiveness. Each protocol, and any subsequent amendments to the protocol, must be submitted to the FDA as part of the IND. Furthermore, each clinical trial must be reviewed and approved by an IRB for each institution at which the clinical trial will be conducted to ensure that the risks to individuals participating in the clinical trials are minimized and are reasonably related to the anticipated benefits. The IRB also approves the informed consent form that must be provided to each clinical trial subject or his or her legal representative, and must monitor the clinical trial until completed.

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The FDA, the IRB, or the sponsor may suspend or discontinue a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk.

Some studies also include oversight by an independent group of qualified experts organized by the clinical study 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 also are requirements governing the reporting of ongoing clinical trials and completed clinical trials to public registries. Information about applicable clinical trials, including clinical trials results, must be submitted within specific timeframes to the National Institutes of Health (NIH) for publication on the www.clinicaltrials.gov website.

Progress reports detailing the results of the clinical trials, among other information, must be submitted at least annually to the FDA and IND safety reports must be submitted to the FDA and the investigators within fifteen days after the trial sponsor determines the information qualifies for reporting for serious and unexpected suspected adverse reactions, findings from other studies or animal or in vitro testing that suggest a significant risk for human participants exposed to the drug or biological product, and any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The sponsor must also notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction as soon as possible, but in no case later than seven calendar days after the sponsor's initial receipt of the information.

A sponsor who wishes to conduct a clinical trial outside of the United States may, but need not, obtain FDA authorization to conduct the clinical trial under an IND. The FDA will accept a well-designed and well-conducted foreign clinical study not conducted under an IND if, among other things, the study was conducted in accordance with GCP, and the FDA is able to validate the data through an onsite inspection if deemed necessary.

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FDA Review Process

Assuming successful completion of the required clinical testing, a BLA requesting approval to market the product for one or more indications must be submitted to FDA. A BLA is a request for approval to market a new biological product for one or more specified indications. The BLA must include all relevant data available from pertinent nonclinical and clinical studies, 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 may come from company-sponsored clinical trials intended to test the safety and efficacy of a product's use or from a number of alternative sources, including studies initiated by investigators not from the company. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety, purity, and potency of the investigational biological product, to the satisfaction of the FDA. FDA approval of a BLA must be obtained before a product may be marketed in the United States.

In addition, under the Pediatric Research Equity Act (PREA) certain BLAs and certain supplements to a BLA must contain data to assess the safety and effectiveness of the product candidate for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective, unless the sponsor has received a deferral or waiver. A sponsor who is planning to submit a marketing application for a product that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration must submit an initial Pediatric Study Plan (iPSP) within 60 days after an End-of-Phase 2 meeting or such other time as agreed upon between FDA and the sponsor. If no End-of-Phase 2 meeting occurs, the iPSP should be submitted as soon as practicable but before initiation of Phase 3 studies, or within 210 calendar days in advance of a marketing application if a Phase 3 study, or a combined Phase 2 and Phase 3 study, will not be conducted or will be conducted but not under IND. Unless otherwise required by regulation, PREA does not apply to a product for an indication for which orphan designation has been granted.

The FDA reviews all submitted BLAs before it accepts them for filing, and may request additional information rather than accepting the BLA for filing. The FDA must make a decision on accepting a BLA for filing within 60 days of receipt, and such decision could include a refusal to file by the FDA. Once the submission is accepted for filing, the FDA begins an in-depth substantive review of the application. The FDA reviews a BLA to determine, among other things, whether the product is safe and effective and whether the facility in which it is manufactured, processed, packaged or held meets standards designed to assure continued safety, quality and purity. Under the goals and polices agreed to by the FDA under the Prescription Drug User Fee Act, as amended (PDUFA) the FDA targets ten months, from the filing date, in which to complete its initial review of an original BLA and respond to the applicant, and six months from the filing date of an original BLA filed for priority review. The FDA does not always meet its PDUFA goal dates for standard or priority BLAs, and the review process may be extended by FDA requests for additional information or clarification.

Further, under the PDUFA, each BLA must be accompanied by a user fee and the sponsor of an approved BLA is also subject to an annual program fee. FDA adjusts the PDUFA user fees on an annual basis. Fee waivers or reductions may be available in certain circumstances, including a waiver of the application fee for the first BLA filed by a small business. Additionally, no user fees are assessed on BLAs for products designated as orphan drugs, unless the product applicant also seeks approval for a non-orphan indication.

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

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

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

After evaluating the application and all related information, including the advisory committee recommendation, if any, and inspection reports regarding the manufacturing facilities and clinical trial sites, the FDA may issue an approval letter, or,

in some cases, a Complete Response Letter. A Complete Response Letter indicates that the review cycle of the application is complete and the application is not ready for approval. A Complete Response Letter will usually describe all of the deficiencies that the FDA has identified in the BLA, except where the FDA determines that the data supporting the application are inadequate to support approval, and the FDA may issue the Complete Response Letter without first conducting required inspections, testing submitted production lots, and/or reviewing proposed labeling. In issuing the Complete Response Letter, the FDA may recommend actions that the applicant might take to place the BLA in condition for approval, including requests for additional information or clarification. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. If and when those conditions have been met to the FDA's satisfaction, the FDA will typically issue an approval letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications.

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

Orphan Drug Designation and Exclusivity

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

A product that has received ODD and subsequently is the first FDA approved biologic product for the disease for which it has such designation, is entitled to orphan product exclusivity for the approved indication. The designation does not convey any advantage in, or shorten the duration of, the regulatory review or approval process. Orphan exclusivity means that the FDA may not approve any other applications, including a full BLA, to market the same drug or biological product for the same indication for seven years from the date of approval of the BLA, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity or if the FDA finds that the holder of the orphan exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan product to meet the needs of patients with the disease or condition for which the product was approved. Orphan exclusivity does not prevent the FDA from approving a different drug

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or biological product for the same disease or condition, or the same product for a different disease or condition. Among the other benefits of ODD are tax credits for certain research and a waiver of the BLA application user fee.

A product that has received ODD may not receive orphan exclusivity if it is approved for a use that is broader than the indication for which it received ODD. In addition, exclusive marketing rights in the United States 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 the patients with the rare disease or condition.

Expedited Development and Review Programs

The FDA maintains several programs intended to facilitate and expedite development and review of new biologic products to address unmet medical needs in the treatment of serious or life-threatening diseases or conditions. These programs include Fast Track Designation (FTD), Breakthrough Therapy Designation (BTD), Priority Review (PR) and Accelerated Approval (AA).

A new biologic product is eligible for FTD if it is intended to treat a serious or life-threatening disease or condition and demonstrates the potential to address unmet medical needs for such disease or condition. FTD applies to the biologic product, or combination of drugs and biologic products, and the specific indication for which it is being studied. FTD may provide increased opportunities for sponsor interactions with the FDA during preclinical and clinical development, in addition to the potential for rolling review once a marketing application is filed, meaning that the FDA may consider for review sections of the BLA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission

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of the sections of the BLA, the FDA agrees to accept sections of the BLA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the application. FDA may revoke the FTD if it believes that the designation is no longer supported by data emerging in the clinical trial process.

In addition, a new biologic product may be eligible for BTD if it is intended to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug or biological product, alone or in combination with or more other biologic products, may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. BTD provides all the features of FTD in addition to intensive guidance on an efficient development program beginning as early as Phase 1, and FDA organizational commitment to expedited development, including involvement of senior managers and experienced review and regulatory staff in a proactive, collaborative, cross-disciplinary review, where appropriate.

Any biologic product submitted to the FDA for approval, including a product with FTD, or BTD, may also be eligible for priority review. A product is eligible for priority review if it is intended to treat a serious condition, and if approved, would provide a significant improvement in safety or effectiveness. For original BLAs, PR Designation means the FDA's goal is to take action on the marketing application within six months of the 60-day filing date (compared with ten months under standard review).

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

AA must meet the same statutory standards for safety and effectiveness as those granted traditional approval. In addition, the FDA currently requires as a condition for AA pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product.

Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. FTD, BTD, PR, and AA do not change the scientific or medical standards for approval or the quality of evidence necessary to support approval but may expedite the development or review process.

U.S. Post-Approval Requirements

Biological products manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, reporting of adverse experiences with the product, complying with promotion and advertising

requirements, which include restrictions on promoting products for unapproved uses or patient populations (off-label use) and limitations on industry-sponsored scientific and educational activities.

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

In addition, product manufacturers and their subcontractors involved in the manufacture and distribution of approved products 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 ongoing regulatory requirements, including cGMP, which imposes certain procedural and documentation requirements upon us and our CMOs. Changes to the manufacturing process are strictly regulated, and often require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting requirements upon the sponsor 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. Failure to comply with statutory and regulatory requirements can subject a manufacturer to possible legal or regulatory action, such as warning letters, suspension of manufacturing, product seizures, injunctions, and civil or criminal penalties. There is also a continuing, annual program fee for any marketed product.

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

The FDA closely regulates the marketing, labeling, advertising and promotion of biologics. 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. 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.

Biosimilars and Reference Product Exclusivity

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the ACA) includes a subtitle called the Biologics Price Competition and Innovation Act (BPCIA), which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. The FDA has issued several guidance documents outlining an approach to review and approval of biosimilars. Biosimilarity, which requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency, can be shown through analytical studies, animal studies, and

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a clinical study or studies, unless the Secretary of Health and Human Services waives a required element. Interchangeability requires that a product is biosimilar to the reference product, and the product must demonstrate that it can be expected to produce the same clinical results as the reference product in any given patient and, for products that are administered multiple times to an individual, the biological product and the reference product may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference product. Complexities associated with the larger, and often more complex, structures of biological products, as well as the processes by which such products are manufactured, pose significant hurdles to approval of biosimilar and interchangeable biosimilar products.

A reference product is granted 12 years of exclusivity from the time of first licensure of the reference product, and an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a BLA for the competing product containing that sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of the other company's product.

At this juncture, it is unclear whether products deemed interchangeable by the FDA will, in fact, be readily substituted by pharmacies, which are governed by state pharmacy law.

A biological product can also obtain pediatric market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods and patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric study, requested by the Secretary, in accordance with an FDA-issued "Written Request" for such a study. However, extensions are not applicable if made later than 9 months prior to the expiration of such period.

Other Regulatory Matters

As further described below, manufacturing, sales, commercialization and promotion of product candidates following product approval and other related activities of the company, where applicable, are subject to regulation by numerous regulatory authorities in the United States in addition to the FDA, which may include the Centers for Medicare and Medicaid Services (CMS), other divisions of the Department of Health and Human Services (HHS), the Department of Justice (DOJ), the Drug Enforcement Administration (DEA), the Consumer Product Safety Commission (CPSC), the Federal Trade Commission (FTC), the Occupational Safety & Health Administration (OSHA), the Environmental Protection Agency (EPA) and state and local governments and governmental agencies.

Other Healthcare Laws

Physicians, other healthcare providers, and third-party payors will play a primary role in the recommendation and prescription of any products for which we obtain marketing approval. Our business operations and any current or future arrangements with third-party payors, healthcare providers and physicians 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 develop, market, sell and distribute any drugs for which we obtain marketing approval. In the United States, these laws include, without limitation:

- The federal Anti-Kickback Statute, an intent-based, federal criminal statute which prohibits, among other things, persons and entities from knowingly and willfully sol offering, paying, receiving or providing any remuneration (including any kickback, bride, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in k

induce or reward, or in return for, either the referral of an individual for, or the purchase, lease, order or arrangement for, or recommendation of, any item or servi which payment may be made, in whole or in part, under by a federal healthcare program such as Medicare or Medicaid. A person or entity need not have knowledge of the federal Anti-Kickback Statute or specific intent to violate it in order to have committed a violation. The term remuneration has been interpreted bro include anything of value. Further, courts have found that if any "one purpose" of the an arrangement involving remuneration is to induce referrals of federal hea program business, the federal Anti-Kickback Statute is has been violated. Violations may be subject to significant civil and criminal fines and penalties for each vio imprisonment, and exclusion from participation in federal healthcare programs. The federal Anti-Kickback Statute applies to arrangements between pharmac manufacturers on the one hand and individuals, such as prescribers, patients, purchasers, and formulary managers on the other hand, including, for ex consulting/speaking arrangements, discount and rebate offers, grants, charitable contributions, and patient support offerings, among others. Although there are a r of statutory exceptions and regulatory safe harbors to the federal Anti-Kickback Statute that protect certain common industry activities from prosecution, these exce and safe harbors are narrowly drawn and arrangements may be subject to scrutiny or penalty if they drawn. Arrangements that do not fully satisfy all elements available exception or safe harbor; harbor are evaluated based on the specific facts and circumstances and are typically subject to increased scrutiny;

- The federal civil and criminal false claims laws, including the civil False Claims Act (FCA), which prohibit individuals or entities from, among other things, kno presenting, or causing to be presented, to the federal government, claims for payment or approval that are false, fictitious or fraudulent; knowingly making, us causing to be made or used, a false statement or record material to a false or fraudulent claim or obligation to pay or transmit money or property to the government; or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay money to the federal government. Manufacturers held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent In addition, Additionally, the ACA specified that any claims submitted as a result of a violation of the federal Anti-Kickback Statute constitute false claims and are sub enforcement under the FCA, and the government may further assert that a claim that includes items or services resulting from a violation of the FDCA federa Kickback Statute, or other law constitutes a false or fraudulent claim for purposes of the FCA. The FCA also permits a private individual acting as a "whistleblower" t *qui tam* actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery or settlement. Violations of the FCA m subject to significant civil fines

and penalties for each false claim, currently ranging from $13,946 - $27,894 per false claim, treble damages, and potential exclusion from participation in federal healthcare programs;

- The federal civil monetary penalties laws, which impose significant civil fines against individuals and entities that engage in activities including, among other knowingly presenting, or causing to be presented, a claim for services not provided as claimed or that is otherwise false or fraudulent in any way; arranging contracting with an individual or entity that is excluded from participation in federal healthcare programs to provide items or services reimbursable by a federal hea program; violations of the federal Anti-Kickback Statute; failing to report and return a known overpayment; or offering or transferring any remuneration to a Medic Medicaid beneficiary if the person knows or should know it is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of ite services reimbursable by Medicare or Medicaid, unless an exception applies;

- The federal criminal statutes enacted under HIPAA, which impose criminal liability for knowingly and willfully executing, or attempting to execute, a scheme to defra healthcare benefit program, including private third-party payors, or to obtain, by means of false or fraudulent pretenses, representations, or promises, any of the mo property owned by, or under the custody or control of, any healthcare benefit program; knowingly and willfully embezzling or stealing from a healthcare benefit pr willfully preventing, obstructing, misleading, or delaying a criminal investigation of a healthcare offense; and knowingly and willfully falsifying, concealing or coverin material fact or making any materially false statements in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the federa Kickback Statute, a person or entity need not have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- HIPAA, The Health Insurance Portability and Accountability Act (HIPAA), as amended by the Health Information Technology for Economic and Clinical Hea ("HITECH") (HITECH), and their respective implementing regulations, imposes, among other things, specified requirements on covered entities and their bu associates relating to the privacy and security of individually identifiable health information including mandatory contractual terms and required implementation of te safeguards of such information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applica business associates in some cases, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions. The Department of Health and Human Services Office for Civil Rights (OCR) has recently increased its enforcement efforts on compliance with HIPAA, including its security regulations, and bringing actions against entities and an business associates for failure to implement required security measures to protect electronic protected health information or to conduct a thorough risk assessment, among other violations;
- The federal Physician Payments Sunshine Act, enacted as part of the ACA, which imposes annual tracking and reporting requirements for, among others, manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Pr for of certain payments and "transfers of value" provided to U.S.-licensed physicians (defined to include doctors, dentists, optometrists, podiatrists and lic chiropractors), physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, anesthesiology assistants, certified midwives, and teaching hospitals, as well as tracking and reporting of ownership and investment interests held by U.S.-licensed physicians and their immediate members; and
- Analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and involving healthcare items or services reimbursed by non-governmental third party-payors, including private insurers, and may be broader in scope than their

equivalents; state and foreign laws requiring pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the re compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; state laws and regulatio require disclosures to state agencies and/or commercial purchasers with respect to certain price increases that exceed a certain level as identified in the relevant st state and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare pro and restrict marketing practices or require disclosure of marketing expenditures and pricing information; state and local laws that require the registration of pharmac sales representatives; and state and foreign laws that govern the privacy and security of health information in some circumstances and which may differ from each o significant ways and often are not pre-empted by HIPAA and may therefore complicate compliance efforts.

The full scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform. Federal and state enforcement bodies have continued to increase their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. It is possible that governmental authorities will conclude that our business practices, including certain arrangements with physicians who receive stock, warrants, or stock options as compensation for services provided to us, do not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other related governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, disgorgement, exclusion from government funded healthcare programs, such as Medicare and Medicaid, reputational harm, additional oversight and reporting obligations if we become subject to a corporate integrity agreement or similar settlement to resolve allegations of non-compliance with these laws and the curtailment or restructuring of our operations. Ensuring business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time- and resource-consuming and can divert a company's attention from its business.

Coverage and Reimbursement

In the United States and markets in other countries, patients who are prescribed treatments for their conditions and providers performing the prescribed services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Patients and healthcare providers are unlikely to use our products unless third-party payor coverage is provided and reimbursement by such payor is adequate to cover a significant portion of the cost of our products. Significant uncertainty exists as to the coverage and reimbursement status of products approved by the FDA and other comparable government authorities. Thus, even if a product candidate is approved, sales of the product will depend, in part, on the extent to which third-party payors, including government health programs in the United States such as Medicare and Medicaid, commercial health insurers and managed care organizations, provide coverage, and establish adequate reimbursement levels for, the product.

Pursuant to the Medicaid Drug Rebate Statute, we will expect to be required to participate in the Medicaid Drug Rebate Program in order for federal payment to be available for our products under Medicaid and Medicare Part B. Medicaid is a government health insurance program for eligible low-income adults, children, families, pregnant women, and people with certain disabilities. It is jointly funded by the federal and state governments, and it is administered by individual states within parameters established by the federal government. As a result, coverage and reimbursement requirements for drugs and biologics vary by state. For example, drugs and biologics may be covered under the medical or pharmacy benefit, and state Medicaid programs may impose different utilization management controls, such as prior authorization, step therapy, or quantity limits on drugs and biologics, subject to federal limitations for such controls. But all states state Medicaid programs must generally provide coverage and reimbursement for a manufacturer's covered outpatient drugs, as that term is defined by applicable law, if a manufacturer participates in the Medicaid Drug Rebate Program.

Under the Medicaid Drug Rebate Program, we will would be required to, among other things, pay a rebate to each state Medicaid program for quantities of our products utilized on an outpatient basis (with some exceptions) that are dispensed to Medicaid beneficiaries and paid for by a state Medicaid program. Medicaid Drug Rebate Program rebates are calculated using a statutory formula, state-reported utilization data, and pricing data that are calculated and reported by us on a monthly and quarterly basis to CMS. These data include the average manufacturer price and, in the case of single source and innovator multiple source products, the best price for each drug.

In addition to participating in the Medicaid Drug Rebate Program, federal law requires manufacturers to participate in the Public Health Service's 340B drug pricing program in order for federal funds to be available for the manufacturer's drugs under Medicaid and Medicare Part B. The 340B drug pricing program requires participating manufacturers to agree to charge statutorily-defined covered entities no more than the 340B "ceiling price" for the manufacturer's covered outpatient drugs. These 340B covered entities only include health care organizations that have certain federal designations or receive funding from specific federal programs, including Federally Qualified Health Centers, Ryan White HIV/AIDS Program grantees, and certain types of hospitals and specialized clinics, as well as certain hospitals that serve a disproportionate share of low-income patients. The Affordable Care Act ACA expanded the 340B program to include additional types of covered entities: certain children's hospitals, certain free-standing cancer hospitals, critical access hospitals, certain rural referral centers and certain sole community hospitals, each as defined by the ACA. However, "orphan drugs" i.e., those designated under section 526 of the FDCA are exempted from the ceiling price requirements for these eligible entities added by the ACA (except for certain children's hospitals). The 340B ceiling price is calculated using a statutory formula, which is based on the average manufacturer price and rebate amount for the covered outpatient drug as calculated under the Medicaid Drug Rebate Program, and in general,

products subject to the Medicaid Drug Rebate Program are also subject to the 340B ceiling price calculation and discount requirement.

In addition, after multiple delays, the final rule implementing civil monetary penalties against manufacturers for instances of overcharging 340B covered entities became effective on January 1, 2019. Accordingly, if we have an approved product, we could be subject to such penalties if the government were to find that we knowingly and intentionally overcharged a 340B covered entity.

Federal law requires that for a company to be eligible to have its products paid for with federal funds under the Medicaid and Medicare Part B programs as well as to be purchased by certain federal agencies and grantees, it also must participate in the Department of Veterans Affairs (VA) Federal Supply Schedule (FSS) pricing program. To participate, we will be required to enter into an FSS contract and other agreements with the VA for our products, which may qualify as “covered drugs.” Under these agreements, we would need to make our products available to the “Big Four” federal agencies—the VA, the Department of Defense (DoD), the Public Health Service (including the Indian Health Service), and the Coast Guard—at prices that are capped pursuant to a statutory federal ceiling price, or FCP, formula set forth in Section 603 of the Veterans Health Care Act of 1992, as amended (VHCA). The FCP is based on a weighted average non-federal average manufacturer price (Non-FAMP), which manufacturers are required to report on a quarterly and annual basis to the VA. Pursuant to the VHCA, knowing provision of false information in connection with a Non-FAMP filing can subject a manufacturer to a penalty for each item of false information and could result in other potential liability as well, including liability under the False Claims Act.

FSS contracts are federal procurement contracts that include standard government terms and conditions, separate pricing for each product, and extensive disclosure and certification requirements. All items on FSS contracts are subject to a standard FSS contract clause that requires FSS contract price reductions under certain circumstances where pricing is reduced to an agreed “tracking customer.” Further, in addition to the “Big Four” federal agencies, all other federal agencies and some non-federal entities are authorized to purchase off FSS contracts. FSS contractors are permitted to charge FSS purchasers other than the Big Four agencies “negotiated pricing” for covered drugs that is not capped by the FCP, and such pricing is negotiated based on a mandatory disclosure of the contractor’s commercial “most favored customer” pricing.

In addition, pursuant to regulations issued by the DoD to implement Section 703 of the National Defense Authorization Act for Fiscal Year 2008, each of our covered drugs will be listed on an agreement with the Defense Health Agency (DHA) under which we will agree to honor the “Big Four” pricing for our products when they are dispensed to TRICARE beneficiaries by TRICARE retail network pharmacies. More specifically, we will agree to provide rebates (or refunds) on such utilization. Companies are required to enter into a DHA Agreement for “covered drug” products in order for the covered drug to be eligible for DoD formulary inclusion and available to TRICARE beneficiaries without preauthorization. The formula for determining the rebate is established in the regulations and our DHA agreement and is based on the difference between the annual Non-FAMP and the FCP (as described above, these price points are required to be calculated by us under the VHCA).

In the United States, no uniform policy of coverage and reimbursement for drug products exists among third-party payors. Therefore, with commercial payors, coverage and reimbursement for drug products can differ significantly from payor to payor. The process for determining whether a third-party payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. Third-party payors are increasingly challenging the prices charged for, examining the medical necessity of, and reviewing the cost-effectiveness of medical products and services. They are also increasingly imposing controls to manage costs. Third-party payors may limit coverage to specific products on an approved list, also known as a formulary, which might not include all of the approved products for a particular indication. Moreover, for products administered under the supervision of a physician, obtaining coverage and adequate reimbursement may be particularly difficult because of the higher prices often associated with such drugs. Additionally, separate reimbursement for the product itself may or may not be available. Instead, the hospital or administering physician may be reimbursed only for providing the treatment or procedure in which our product is used.

In order to secure coverage and reimbursement for any product that might be approved for sale, a company may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the product, in addition to the costs required to obtain FDA or other comparable regulatory approvals. Obtaining coverage and reimbursement approval of a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide to each payor supporting scientific, clinical and cost-effectiveness data for the use of our products

on a payor-by-payor basis, with no assurance that coverage and adequate reimbursement will be obtained. Nonetheless, product candidates may not be considered medically necessary or cost-effective. A decision by a third-party payor not to cover a product could reduce physician utilization once the product is approved and have a material adverse effect on sales, our operations and financial condition. Additionally, a third-party payor’s decision to provide coverage for a product does not imply that an adequate reimbursement

rate will be approved. Further, one payor's determination to provide coverage for a product does not assure that other payors will also provide coverage and reimbursement for the product, and the level of coverage and reimbursement can differ significantly from payor to payor. Third-party coverage and reimbursement may not be available to enable us to maintain price levels sufficient to cover our costs, including research, development, manufacture, sale and distribution distribution.

The containment of healthcare costs also has become a priority of federal, state and foreign governments, and the prices of products have been a focus in this effort. Governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on 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 a company's revenue generated from the sale of any approved products.

Coverage policies and third-party payor reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which a company or its collaborators receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future. It is difficult to predict how Medicare coverage and reimbursement policies will be applied to products for which the company receives marketing approval in the future and coverage and reimbursement under different federal healthcare programs is not always consistent. Further, private payors often follow the coverage and reimbursement policies established under Medicare. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our products for which we receive marketing approval.

Healthcare Reform

In the United States and some foreign jurisdictions, there have been, and likely will continue to be, a number of legislative and regulatory changes and proposed changes regarding the healthcare system directed at broadening the availability of healthcare, improving the quality of healthcare, and containing or lowering the cost of healthcare. For example, in March 2010, the United States Congress enacted the ACA, which, among other things, included changes to the coverage and payment for products under government health care programs. The ACA included provisions of importance to our potential product candidate that:

- created an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic products, apportioned among entities according to their market share in certain government healthcare programs;
- expanded eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to certain individuals with income at or below of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability;
- expanded manufacturers' rebate liability under the Medicaid Drug Rebate Program by increasing the minimum rebate for both branded and generic drugs and revis definition of "average manufacturer price," or AMP, for calculating and reporting Medicaid drug rebates on outpatient prescription drug prices;
- addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, ir instilled, implanted or injected;
- expanded the types of entities eligible for the 340B drug discount program; and
- created a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with f for such research.

Since its enactment, there have been judicial, executive and congressional challenges to certain aspects of the ACA. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the ACA have been signed into law, including the repeal, effective January 1, 2019, of the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states who argued that, without the individual mandate, the entire ACA was unconstitutional. The Supreme Court's dismissal of the lawsuit did not specifically rule on the constitutionality of the ACA. It

is unclear how other healthcare reform measures of the Biden administration or other efforts, if any, to challenge, repeal or replace the ACA will impact the ACA or our business.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted to reduce healthcare expenditures. These changes include the Budget Control Act of 2011, which, among other things, included aggregate reductions of Medicare payments to providers of 2% per fiscal year, which went into effect in April 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2031 the first six months of the FY 2032 sequestration order unless additional congressional action is taken, with the exception of a temporary suspension by Congress of the 2% cut in Medicare payments from May 1, 2020 through March 31, 2022, with a 1% cut in Medicare payments in effect from March 31, 2022 to July 1, 2022, due to the COVID-19 pandemic. public health emergency. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Moreover, payment methodologies may be subject to changes under new healthcare legislation and regulatory initiatives. For example, CMS may develop new payment and delivery models, such as bundled payment models. In addition, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their commercial products, which has resulted in several congressional inquiries and proposed and enacted state and federal legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for pharmaceutical products. For example, included in the Consolidated Appropriations Act, 2021 were several drug price reporting and transparency measures, such as a new requirement for certain Medicare plans to develop tools to display Medicare Part D prescription drug benefit information in real time and for group and health insurance issuers to report information on pharmacy benefit and drug costs to the Secretaries of HHS, Labor and the Treasury. Moreover, in August 2022, President Biden signed into law the Inflation Reduction Act of 2022 (the "IRA") (IRA), which implements substantial changes to the Medicare program, including drug pricing reforms and the creation of new Medicare inflation rebates. Namely, the IRA imposes inflation rebates on drug manufacturers for products reimbursed under Medicare Parts B and D if the prices of those products increase faster than inflation; implements changes to the Medicare Part D benefit that, beginning in 2025, will cap beneficiary annual out-of-pocket spending at $2,000, while imposing new discount obligations for pharmaceutical manufacturers; and, beginning in 2026, establishes a "maximum fair price" for a fixed number of high expenditure pharmaceutical and biological products covered under Medicare Parts B and D following a price negotiation process with CMS. On CMS has also taken steps to implement the IRA, including: on June 30, 2023, issuing guidance detailing the requirements and parameters of the first round of price negotiations, to take place during 2023 and 2024, for products subject to the "maximum fair price" provision that would become effective in 2026; on August 29, 2023, releasing the initial list of ten drugs subject to price negotiations; on November 17, 2023, releasing guidance outlining the methodology for identifying certain manufacturers eligible to participate in a phase-in period where discounts on applicable products will be lower than those required by the Medicare Part D Manufacturer Discount Program; and on December 14, 2023, releasing a list of 48 Medicare Part B products that had an adjusted coinsurance rate based on the inflationary rebate provisions of the IRA for the period of January 1, 2024 to March 31, 2024. Additionally, on October 14, 2022, President Biden issued an Executive Order on Lowering Prescription Drug Costs for Americans, which instructed the Secretary of HHS to consider whether to select for testing by the CMS Innovation Center new health care payment and delivery models that would lower drug costs and promote access to innovative drug therapies for beneficiaries enrolled in the Medicare and Medicaid programs. Most recently, on On February 14, 2023, HHS issued a report in response to the October 14, 2022 Executive Order, which, among other things, selects three potential drug affordability and accessibility models to be tested by the CMS Innovation Center. Specifically, the report addresses: (1) a model that would allow Part D Sponsors to establish a "high-value drug list" setting the maximum co-payment amount for certain common generic drugs at $2.00; (2) a Medicaid-focused model that would establish a partnership between CMS, manufacturers, and state Medicaid agencies that would result in multi-state outcomes-based agreements or certain cell and gene therapy drugs; and (3) a model that would adjust Medicare Part B payment amounts for Accelerated Approval Program drugs to advance the developments of novel treatments. In addition on February 2, 2022, the Biden administration signaled its continued commitment to the Cancer Moonshot initiative, which was initially launched in 2016. In its announcement, the administration noted that its new goals under the initiative include addressing inequities in order to ensure broader access to cutting-edge cancer therapeutics and investing in a robust pipeline for new treatments. In alignment with President Biden's Cancer Moonshot initiative, on June 27, 2023, the Center for Medicare Innovation at CMS announced a new model, the Enhancing Oncology Model, that is designed to make high-quality cancer care more affordable to both patients and Medicare. We expect that additional U.S. federal healthcare reform measures will be adopted in the future, any of which could limit the extent to which the U.S. federal government covers particular healthcare products and services and could limit the amounts that the U.S. federal government will pay for healthcare products and services. This could result in reduced demand for our product candidates or additional pricing pressures. At the state level, individual states have also increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize any product that is ultimately approved, if approved.

On May 30, 2018, the Right to Try Act was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase 1 clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a drug manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act, but the manufacturer must develop an internal policy and respond to patient requests according to that policy.

Outside the United States, ensuring coverage and adequate payment for a product also involves challenges. Pricing of prescription pharmaceuticals is subject to government control in many countries. Pricing negotiations with government

authorities can extend well beyond the receipt of regulatory approval for a product and may require a clinical trial that compares the cost-effectiveness of a product to other available therapies. The conduct of such a clinical trial could be expensive and result in delays in commercialization.

In the European Union, EU, pricing and reimbursement schemes vary widely from country to country. Some countries provide that products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost-effectiveness of a particular product candidate to currently available therapies or so-called health technology assessments, in order to obtain reimbursement or pricing approval. For example, the European Union EU provides options for its EU Member States to restrict the range of products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. EU Member States may approve a specific price for a product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the product on the market. Other Member States allow companies to fix their own prices for products, but monitor and control prescription volumes and issue guidance to physicians to limit prescriptions. Recently, many countries in the European Union EU have increased the amount of discounts required on pharmaceuticals and these efforts could continue as countries attempt to manage healthcare expenditures, especially in light of the severe fiscal and debt crises experienced by many countries in the European Union. EU. The downward pressure on healthcare costs in general, particularly prescription products, has become intense. As a result, increasingly high barriers are being erected to the entry of new products. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various EU Member States, and parallel trade, i.e., arbitrage between low-priced and high-priced EU Member States, can further reduce prices. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any products, if approved in those countries.

Compliance with Other Federal and State Laws or Requirements; Changing Legal Requirements

If any products that we may develop are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. Products must meet applicable child-resistant packaging requirements under the U.S. Poison Prevention Packaging Act. Manufacturing, labeling, packaging, distribution, sales, promotion and other activities also are potentially subject to federal and state consumer protection and unfair competition laws, among other requirements to we may be subject.

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

The failure to comply with any of these laws or regulatory requirements may subject us 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, exclusion from federal healthcare programs, requests for recall, seizure of products, total or partial suspension of production, denial or withdrawal of product approvals, relabeling or repackaging, or refusal to allow a company to enter into supply contracts, including government contracts. Any claim or action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. Prohibitions or restrictions on marketing, 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 sales and manufacturing arrangements; (ii) additions or modifications to product labeling or packaging; (iii) the recall or discontinuation of our products; or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business.

European Union Drug Development

In the EU, our future products also may be subject to extensive regulatory requirements. As in the United States, medicinal products can only be marketed if a Marketing Authorization (MA) from a competent regulatory authority has been obtained and additionally, the various phases of preclinical and clinical research in the EU are subject to significant regulatory controls.

European Union Clinical Trials

For example, in the EU, a clinical trial application (CTA) must be submitted to each EU Member State's competent authority and an independent ethics committee, similar to the FDA and the IRB, respectively. The CTA must include, among other things, a copy of the trial protocol and an investigational medicinal product dossier containing information about the manufacture and quality of the medicinal product under investigation. Once the CTA is approved by the EU Member State's competent authority and the ethics committee has granted a positive opinion in relation to the conduct of the trial in the relevant Member State(s), in accordance with an EU Member State's requirements, clinical trial development may proceed.

Clinical trials of medicinal products in the EU must be conducted in accordance with EU and EU Member State regulations and the International Conference on Harmonization (ICH) guidelines on GCP, as well as the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki. Additional GCP guidelines from the European Commission, focusing in particular on traceability, apply to clinical trials of advanced therapy medicinal products. If the sponsor of the clinical trial is not established within the EU, it must appoint an entity within the EU to act as its legal representative. The sponsor must take out a clinical trial insurance policy, and in most EU Member States, the sponsor is liable to provide 'no fault' compensation to any study subject injured in the clinical trial.

In the European Union, or the EU, the Clinical Trials Regulation ((EU) No 536/2014) applied since 31 January 2022, replacing and repealing the Clinical Trials Directive (2001/20/EC). Under the Clinical Trials Regulation (EU) No 536/2014, there is a centralized application procedure where one EU Member State's competent authority takes the lead in reviewing part I of the application, which contains scientific and medicinal product documentation, and the other national authorities only have limited involvement. Part II, which contains the national and patient-level documentation, will be assessed individually by each EU Member State. A clinical trial can only start in an EU Member State once it has been authorized (potentially with conditions) by the concerned EU Member State via the EU Clinical Trials Information System (CTIS). Separately, the sponsor must obtain a positive opinion from the relevant, independent Ethics Committee(s). A transitional period will apply during the transition from Clinical Trials Directive to the Clinical Trials Regulation, During this period, the following applies: (a) from January 31, 2023, clinical trial sponsors will need to use CTIS to apply to start a new clinical trial in the EU/EEA; and (b) from January 31, 2025, any trials approved under the Clinical Trials Directive that continue running will need to comply with the Clinical Trials Regulation and their sponsors must have recorded information on them in the CTIS.

Any substantial changes to the trial protocol or other information submitted with the CTA must be notified to or approved by the relevant competent authorities and ethics committees. Medicines used in clinical trials must be manufactured in accordance with GMP. Other national and EU-wide regulatory requirements may also apply.

During the development of a medicinal product, the EMA and EU Member States' competent authorities provide the opportunity for dialogue and guidance on the development program. At the EMA level, this is usually done in the form of scientific advice, which is given by the CHMP. A fee is incurred with each scientific advice procedure. Advice from the EMA is typically provided based on questions concerning, for example, quality (chemistry, manufacturing and controls testing), nonclinical testing and clinical trials, and pharmacovigilance plans and risk-management programs. Advice is not legally binding with regard to any future MAA of the product concerned.

We are in the process of applying to renew our status with the EMA as a small and medium-sized enterprise (SME). If we are successful in maintaining our current SME status with the EMA, it will provide access to administrative, regulatory and financial support, including fee reductions for scientific advice and regulatory procedures.

European Union Drug Review and Approval

In the European Union, EU, medicinal products can only be placed on the market after obtaining a MA. To obtain regulatory approval of an investigational biological product in the EU, we must submit an MAA. The application used to file the BLA in the United States is similar to that required in the European Union, EU, with the exception of, among other things, country-specific document requirements. The process for doing this depends, among other things, on the nature of the medicinal product.

The centralized procedure results in a single MA, issued by the European Commission (based on the opinion of the EMA), which is valid across the entire territory of the EU. The centralized procedure is compulsory for human drugs that are: (1) derived from biotechnology processes, such as genetic engineering, (2) contain a new active substance indicated for the treatment of certain diseases, such as HIV/AIDS, cancer, diabetes, neurodegenerative diseases, autoimmune and other immune

dysfunctions and viral diseases, (3) designated orphan medicines and/or (4) advanced-therapy medicines, such as gene therapy, somatic cell therapy or tissue-engineered medicines. The centralized procedure may, at the request of the applicant, also be

used in certain other cases. Therefore, the centralized procedure would be mandatory for the products we are developing.

The CAT is responsible in conjunction with the CHMP for the evaluation of ATMPs. The CAT is primarily responsible for the scientific evaluation of ATMPs and prepares a draft opinion on the quality, safety and efficacy of each ATMP for which a MAA is submitted. The CAT's opinion is taken into account by the CHMP when giving its final recommendation regarding the authorization of a product in view of the balance of benefits and risks identified. Although the CAT's draft opinion is submitted to the CHMP for final approval, the CHMP may depart from the draft opinion, if it provides detailed scientific justification. The CHMP and CAT are also responsible for providing guidelines on ATMPs and have published numerous guidelines, including specific guidelines on gene therapies and cell therapies. These guidelines provide additional guidance on the factors that the EMA

will consider in relation to the development and evaluation of ATMPs and include, among other things, the preclinical studies required to characterize ATMPs; the manufacturing and control information that should be submitted in a MAA; and post-approval measures required to monitor patients and evaluate the long term efficacy and potential adverse reactions of ATMPs.

Under the centralized procedure, the maximum timeframe for the evaluation of a MAA by the EMA is 210 days. This excludes so-called clock stops, during which additional written or oral information is to be provided by the applicant in response to questions asked by the EMA. At the end of the review period, the EMA provides an opinion to the European Commission. If this opinion is favorable, the European Commission may then adopt a decision to grant an MA.

MAs have an initial duration of five years. After these five years, the authorization may be renewed on the basis of a reevaluation of the risk-benefit balance. Once renewed, the MA is valid for an unlimited period unless the European Commission or the EU Member States' competent authority decides, on justified grounds relating to pharmacovigilance, to proceed with one additional five-year renewal.

In exceptional cases, the EMA might perform an accelerated review of an MAA in no more than 150 days (not including clock stops). Innovative products that target an unmet medical need and are expected to be of major public health interest may be eligible for a number of expedited development and review programs, such as the Priority Medicines (PRIME) scheme, which provides incentives similar to BTD in the U.S. PRIME is a voluntary scheme aimed at enhancing the EMA's support for the development of medicines that target unmet medical needs. It is based on increased interaction and early dialogue with companies developing promising medicines, to optimize their product development plans and speed up their evaluation to help them reach patients earlier. Product developers that benefit from PRIME designation can expect to be eligible for accelerated assessment but this is however not guaranteed. The benefits of a PRIME designation include the appointment of a rapporteur from the EMA before submission of an MAA, early dialogue and scientific advice at key development milestones, and the potential to qualify products for accelerated review earlier in the application process.

The European Commission may grant a so-called "conditional marketing authorization" prior to obtaining the comprehensive clinical data required for an application for a full MA. Such conditional MAs may be granted for product candidates (including medicines designated as orphan medicinal products), if (1) the risk-benefit balance of the product candidate is positive; (2) it is likely that the applicant will be in a position to provide the required comprehensive clinical trial data; (3) the product fulfills an unmet medical need; and (4) the benefit to public health of the immediate availability on the market of the medicinal product concerned outweighs the risk inherent in the fact that additional data are still required. A conditional MA may contain specific obligations to be fulfilled by the MA holder, including obligations with respect to the completion of ongoing or new studies and the collection of pharmacovigilance data. Conditional MAs are valid for one year, and may be renewed annually if the risk-benefit balance remains positive and after an assessment of the need for additional or modified conditions and/or specific obligations. The MA can be converted into a standard MA once the MA holder fulfils the obligations that were imposed and the complete data confirm that the medicine's benefits continue to outweigh its risks. The timelines for the centralized procedure described above also apply with respect to the review by the EMA of applications for a conditional MA.

The European Commission may also grant a so-called "marketing authorization under exceptional circumstances." Such MA is intended for products for which the applicant can demonstrate that it is unable to provide comprehensive data on the efficacy and safety under normal conditions of use even after the product has been authorized because (1) the indications for which the product in question is intended are encountered so rarely that the applicant cannot reasonably be expected to provide comprehensive evidence; (2) in the present state of scientific knowledge, comprehensive information cannot be provided; or

(3) it would be contrary to generally accepted principles of medical ethics to collect such information. Consequently, MAs under exceptional circumstances may be granted subject to certain specific obligations, which may include the following:

- the applicant must complete an identified program of studies within a time period specified by the competent authority, the results of which form the basi reassessment of the benefit/risk profile;

- the medicinal product in question may be supplied on medical prescription only and may in certain cases be administered only under strict medical supervision, pos a hospital and in the case of a radio-pharmaceutical, by an authorized person; and
- the package leaflet and any medical information must draw the attention of the medical practitioner to the fact that the particulars available concerning the me product in question are as yet inadequate in certain specified respects.

An MA under exceptional circumstances is subject to annual review to reassess the risk-benefit balance in an annual reassessment procedure. Continuation of the authorization is linked to the annual reassessment and a negative assessment could potentially result in the MA being suspended or revoked. The renewal of a MA of a medicinal product under exceptional circumstances, however, follows the same rules as a "normal" MA. Thus, a MA under exceptional circumstances is granted for an initial five years, after which the authorization will become valid indefinitely, unless the EMA decides that safety grounds merit one additional five-year renewal. A MA under exceptional circumstances should not be granted when a conditional MA is more appropriate.

The European Union EU medicines rules expressly permit the EU Member States to adopt national legislation prohibiting or restricting the sale, supply or use of any medicinal product containing, consisting of or derived from a specific type of human or animal cell, such as embryonic stem cells. While the products we have in development do not make use of embryonic stem cells, it is possible that the national laws in certain EU Member States may prohibit or restrict us from commercializing our products, even if they have been granted an MA.

European Union Data and Marketing Exclusivity

The EU also provides opportunities for market exclusivity. MAAs for generic medicinal products do not need to include the results of preclinical and clinical trials, but instead can refer to the data included in the MA of a reference product for which regulatory data exclusivity has expired. Upon receiving an MA, new chemical entities generally receive eight years of data exclusivity and an additional two years of market exclusivity. If granted, data exclusivity prevents regulatory authorities in the European Union EU from referencing the innovator's data to assess a generic or biosimilar application. During the additional two-year period of market exclusivity, a generic marketing authorization can be submitted, and the innovator's data may be referenced, but no generic or biosimilar product can be marketed until the expiration of the market exclusivity. The overall ten-year market exclusivity period may be extended to a maximum of eleven years if, during the first eight years a new therapeutic indication with significant clinical benefit over existing therapies is approved. However, there is no guarantee that a product will be considered by the EU regulatory authorities to be a new chemical entity, and products may not qualify for data exclusivity.

On April 26, 2023, the European Commission published proposals to revise the existing EU legislation on pharmaceutical products (the EU Pharma Law Review). These proposals comprise a new directive and a new regulation (the EU Pharma Law Proposal) that will replace the current legislation concerning medicinal products for human use, including legislation concerning orphan medical products and medicinal products for pediatric use. The EU Pharma Law Review could have a significant impact on the regulatory data exclusivity protection (RDP) for innovative pharmaceutical products in the EU. If adopted in current form, the EU Pharma Law Proposal would reduce the current baseline for data exclusivity from eight to six years, extendable under certain conditions. Such RDP reduction could lead to faster access to the EU market for generics and biosimilars.

European Union Orphan Drug Designation and Exclusivity

Products receiving orphan drug designation in the EU can receive ten years of market exclusivity once they are authorized as orphan medicines. During the ten-year market exclusivity period, the EMA cannot accept another application for a MA, or grant a MA or accept an application to extend an existing MA, for the same therapeutic indication, in respect of a similar medicinal product. An orphan medicinal product can also obtain an additional two years of market exclusivity in the EU for pediatric studies. No extension to any supplementary protection certificate can be granted on the basis of pediatric studies for orphan indications.

The criteria for designating an "orphan medicinal product" in the EU are similar in principle to those in the United States. A medicinal product may be designated as orphan if (1) it is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition; (2) either (a) such condition affects no more than five in 10,000 persons in the European Union EU when the application is made, or (b) the product, without the benefits derived from orphan status, would not generate sufficient return in the EU to justify investment; and (3) there exists no satisfactory method of diagnosis, prevention or treatment of such condition authorized for marketing in the EU, or if such a method exists, the product will be of significant benefit to those affected by the condition. Orphan medicinal products are eligible for financial incentives such as reduction of fees or fee waivers. The application for orphan drug designation must be submitted before the MAA. The applicant will receive a fee reduction for the MAA if the orphan drug designation has been granted, but not if the designation is still pending at the time

time the MA is submitted. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

The ten-year market exclusivity may be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan drug designation, for example, if the product is sufficiently profitable not to justify maintenance of market exclusivity. Additionally, a MA may be granted to a similar product for the same indication at any time if:

(1) the second applicant can establish that its product, although similar, is safer, more effective or otherwise clinically superior;

(2) the holder of the MA for the original orphan medicinal product has given its consent to the second applicant; or

(3) the holder of the MA for the original orphan medicinal product is unable to supply sufficient quantities of the medicinal product.

The EU Pharma Law Review could have a significant impact on the designation of orphan medicinal products in the EU and the incentives offered for the development of these products. If adopted in current form, the EU Pharma Law Proposal would introduce the possibility for the European Commission to derogate by way of delegated acts from the current prevalence criterion and impose specific criteria for certain conditions depending on the characteristics of these conditions or other scientific reasons. The EU Pharma Law Proposal also proposes changes to the current orphan market exclusivity (OME) approach. If adopted in the current form, the EU Pharma Law Proposal would in most cases reduce the duration of the OME, and replace the current system with separate OME periods for each new indication, to a system with a single OME period for each active substance.

Post-Approval Requirements

Similar to the United States, both marketing authorization holders and manufacturers of medicinal products are subject to comprehensive regulatory oversight by the EMA, the European Commission and/or the EU Member States' competent authorities. The holder of an MA must establish and maintain a pharmacovigilance system and appoint an individual qualified person for pharmacovigilance who is responsible for oversight of that system. Key obligations include expedited reporting of suspected serious adverse reactions and submission of periodic safety update reports, (PSURs).

All new MAAs must include a RMP describing the risk management system that the company will put in place and documenting measures to prevent or minimize the risks associated with the product. The regulatory authorities may also impose specific obligations as a condition of the MA. Such risk-minimization measures or post-authorization obligations may include additional safety monitoring, more frequent submission of PSURs, or the conduct of additional clinical trials or post-authorization safety studies.

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

European Union Drug Marketing

The advertising and promotion of medicinal products is also subject to laws concerning promotion of medicinal products, interactions with physicians, misleading and comparative advertising and unfair commercial practices. All advertising and promotional activities for the product must be consistent with the approved summary of product characteristics, and therefore all off-label promotion is prohibited. Direct-to-consumer advertising of prescription medicines is also prohibited in the EU. Although general requirements for advertising and promotion of medicinal products are established under EU Directives, the details are governed by regulations in each EU Member State and can differ from one country to another.

Much like the Anti-Kickback Statue prohibition in the United States, the provision of benefits or advantages to healthcare professionals to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is also prohibited in the EU. The provision of benefits or advantages to physicians is governed by the national anti-bribery rules of EU Member States. Infringement of these laws could result in substantial fines and imprisonment.

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Payments made to healthcare professionals in certain EU Member States must be publicly disclosed. Moreover, agreements with healthcare professionals often must be the subject of prior notification and approval by the healthcare professional's employer, his or her competent professional organization and/or the regulatory authorities of the individual EU Member States. These requirements are provided in the national laws, industry codes or professional codes of conduct, applicable in the EU Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative or criminal penalties, including fines, or imprisonment.

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Pricing and Reimbursement

Even if a medicinal product obtains a MA in the EU, there can be no assurance that reimbursement for such product will be secured on a timely basis or at all. Governments influence the price of medicinal products through their pricing and reimbursement rules and control of national healthcare systems that fund a large part of the cost of those products to consumers. EU Member States are free to restrict the range of pharmaceutical products for which their national health insurance systems provide reimbursement, and to control the prices and reimbursement levels of pharmaceutical products for human use. Some jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed to by the government. EU Member States may approve a specific price or level of reimbursement for the pharmaceutical product, or alternatively adopt a system of direct or indirect controls on the profitability of the company responsible for placing the pharmaceutical product on the market, including volume-based arrangements, caps and reference pricing mechanisms. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials in order to compare the cost-effectiveness of a particular product candidate to currently available therapies. Other EU Member States may allow companies to fix their own prices for medicines, but monitor and control company profits. The downward pressure on healthcare costs in general, particularly prescription medicines, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross border imports from low-priced markets exert a commercial pressure on pricing within a country. In December 2021, Regulation (EU) 2021/2282 on HTA (the "HTA Regulation") (HTA Regulation) was adopted. The HTA Regulation will apply beginning on January 12, 2025. It replaces the current system based on the voluntary network of national authorities, and the new framework covers joint clinical assessments, joint scientific consultations, the identification of emerging health technologies, and voluntary cooperation for the national authorities. The HTA Regulation aims to provide a transparent and inclusive framework for health technology assessments in the EU, and it will help EU countries determine the effectiveness and value of new technologies and decide on pricing and reimbursement by health insurers or health systems.

European Pediatric Investigation Plan

In the EU, MAAs for new medicinal products must generally include the results of studies conducted in the pediatric population in compliance with a pediatric investigation plan (PIP) agreed with the EMA's Pediatric Committee (PDCO). The PIP sets out the timing and measures proposed to generate data to support a pediatric indication of the drug for which an MA is being sought. The PDCO can grant a deferral of the obligation to implement some or all of the measures of the PIP until there are sufficient data to demonstrate the efficacy and safety of the medicinal product in adults. Further, the obligation to provide pediatric clinical trial data can be waived by the PDCO when this data is not needed or appropriate because the product is likely to be ineffective or unsafe in children, the disease or condition for which the product is intended occurs only in adult populations, or when the product does not represent a significant therapeutic benefit over existing treatments for pediatric patients. Once the MA is obtained in all Member States of the EU and trial results are included in the product information, the product is eligible for six months' supplementary protection certificate extension.

The EU Pharma Law Review could have a significant impact on pediatric medicinal products. If adopted in the current form, the EU Pharma Law Proposal would introduce a new evolutionary pediatric investigation plans (PIPs) system for certain types of developments, allowing the submission of an initial high level PIP, to be subsequently completed at precise stages in the development. The greater flexibility granted by this step-wise approach could be offset by the more stringent scrutiny over PIPs by the EMA. In addition, the EU Pharma Law Proposal could introduce the obligation to place medicinal products authorized for a pediatric indication on the market of all EU Member States where the medicinal product is already placed on the market.

European Data Collection

The collection and use of personal data (including health data) in the EEA is governed by the EU General Data Protection Regulations (GDPR) and national implementing legislation in EEA States. The EU GDPR applies to any company established in the EEA and to companies established outside the EEA that process personal data in connection with the offering of goods or services to data subjects in the EEA or the monitoring of the behavior of data subjects in the EEA. The EU GDPR establishes stringent requirements applicable to the processing of personal data, including strict requirements relating to the validity of consent of data subjects, expanded disclosures about how personal data is used, requirements to conduct data protection impact assessments for "high risk" processing, limitations on retention of personal data, special provisions for the processing of "special categories of personal data" including health and genetic information of data subjects, mandatory data breach notification (in certain circumstances), "privacy by design" requirements, and direct obligations on service providers acting as processors. The EU GDPR also prohibits the international transfer of personal data from the EEA to countries outside of the EEA unless made to a country deemed to have adequate data privacy laws by the European Commission or a data transfer mechanism has been put in place. Failure to comply with the requirements of the EU GDPR and the related national data protection laws of the EEA States may result in fines up to €20 million or 4% of a company's global annual revenues for the preceding financial year, whichever is higher. Moreover, the EU GDPR affords various data protection rights to individuals (e.g., the right to erasure of personal data) in certain circumstances, and the ability for data subjects to claim material and non-material damages resulting from infringements of the EU GDPR. Given the breadth and depth of changes in data protection obligations, maintaining compliance with the EU GDPR, will require significant time, resources and expense, and we may be required to put in place additional mechanisms ensuring compliance with the evolving data protection rules. This may be onerous and adversely affect our business, financial condition, results of operations and prospects. These requirements and risks are set out in further detail in the section of this annual report titled "Risk Factors—Risks Related to Our Industry and

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Business Operations—We are subject to a variety of privacy and data security laws, and our failure to comply with them could harm our business."

Rest of the World Regulation

For other countries outside of the EU (or in some cases, EEA) and the United States, such as the United Kingdom, countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. Additionally, the clinical trials must be conducted in accordance with GCP requirements and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Employees and Human Capital Resources

As of December 31, 2022 December 31, 2023, we had 57 68 full-time employees, 23 22 of whom have Ph.D. or M.D. degrees. Of these full-time employees, 42 52 employees are engaged in research and development activities and 15 16 employees are engaged in finance, legal, human resources, investor relations, IT, facilities and general management. We have no collective bargaining agreements with our employees and we have not experienced any work stoppages. We consider our relationship with our employees to be good.

Our human capital resources objectives include as applicable, identifying, recruiting, retaining, incentivizing and integrating our employees. We also place a high value on the diversity of our team, – including gender, background and expertise – in order to foster our a culture of innovation. The principal purposes of our equity incentive plans are to align the interests of our stockholders and those eligible for awards, to retain and incentivize officers, directors, employees, and other service providers, and to encourage them to act in our long-term best interests. We value our employees and regularly evaluate total compensation we provide, including pension contributions paid time off personal leave and other benefits, to ensure we remain competitive and attractive to potential new hires.

Facilities

We lease a facility containing approximately 622 square meters of office space for our main office, which is located at COBIS, Ole Maaloes Maaløes Vej 3, 2200 DK-2200 Copenhagen N, Denmark. The lease expires on December 31, 2027. in December 2027. We also lease lab space at COBIS, Ole Maaloes Maaløes Vej 3, 2200 DK-2200 Copenhagen N, Denmark. The initial lease expired on December 31, 2022 and a new lease commenced on January 1, 2023, which expires on December 31, 2027. in December 2027.

In the United States, we lease a facility in New York for office space, located at 430 East 29th Street, New York, New York, and a facility in Maryland for lab space, located at 5640 Fishers Lane, Suite C, Rockville, Maryland. The New York lease expires on February 28, 2027 in January 2027 and the Maryland lease expires on March 31, 2027. in May 2027.

For our UK team, we lease an office facility space located at 18 Maryport Street, Monmouthshire, No 1 Langstone Business Park, Newport, UK. This The lease can be terminated at our convenience. expires in May 2025.

We believe that our current facilities are adequate for our current needs and that suitable additional or substitute space at commercially reasonable terms will be available as needed to accommodate any future expansion of our operations.

Corporate Information

We were incorporated under the laws of the State of Delaware on May 25, 2021 under the name IO Biotech, Inc. We consummated a corporate reorganization in connection with our initial public offering (IPO), pursuant to which all of the issued and outstanding stock of IO Biotech ApS (IO ApS) was exchanged for shares of Class A and preferred stock of IO Biotech, Inc. As a result of this the corporate reorganization, IO ApS, became a wholly-owned subsidiary of IO Biotech, Inc. We are a holding company. We conduct substantially all of our operations through our subsidiaries. Our subsidiary, IO Biotech ApS, a corporation domiciled in Denmark, was originally incorporated in December 2014, and holds our intellectual property assets. Our executive offices are located at Ole Maaløes Vej 3, DK-2200 Copenhagen N, Denmark, and our telephone number is +45 7070 2980. Our website address is iobiotech.com. Information contained on, or that can be accessed through, our website is

not incorporated by reference into this Annual Report on Form 10-K, and you should not consider information on our website to be part of this Annual Report on Form 10-K.

Item 1A. Risk Factors.

Our business is subject to numerous risks. You should carefully consider the following risks and all other information contained in this Annual Report, as well as general economic and business risks, together with any other documents we file with the SEC. If any of the following events actually occur or risks actually materialize, it could have a material adverse effect on our business, operating results and financial condition and cause the trading price of our common stock to decline.

Risks Related to Limited Operating History, Financial Position and Capital Requirements

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

We are a clinical-stage biopharmaceutical company with a limited operating history that may make it difficult to evaluate the success of our business to date and to assess our future viability. Our operations to date have been limited to organizing and staffing our company, business planning, raising capital, developing and optimizing our technology platform, identifying potential product candidates, undertaking research, preclinical studies and clinical trials for our product candidates, establishing and enhancing our intellectual property portfolio, and providing general and administrative support for these operations. IO102-IO103 is in early clinical development and IO112 is in preclinical development, and none of our product candidates have been approved for commercial sale. We have never generated any revenue from product sales and have incurred net losses each year since we commenced operations. For the years ended December 31, 2022 December 31, 2023 and 2021, 2022, our net losses were $71.5 million $86.1 million and $67.9 million $71.5 million, respectively. We expect that it will be several years, if ever, before we have a product candidate ready for regulatory approval and commercialization. We expect to incur increasing levels of operating losses over the next several years and for the foreseeable future as we advance our product candidates through clinical development. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders' deficit and working capital.

To become and remain profitable, we must develop and eventually commercialize a product or products with significant market potential. This will require us to be successful in a range of challenging activities, including completing preclinical studies and clinical trials of our product candidates, obtaining marketing approval for these product candidates, manufacturing, marketing and selling those products for which we may obtain marketing approval and satisfying any post-marketing requirements. We may never succeed in these activities and, even if we succeed in commercializing one or more of our product candidates, we may never generate revenue that is significant or large enough to achieve profitability. In addition, as a young business, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown challenges. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis and we will continue to incur substantial research and development and other expenditures to develop and market additional product candidates. Our failure to become and remain profitable would decrease the value of the company and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations. A decline in the value of our company could also cause our stockholders to lose all or part of their investment.

We will need to obtain substantial additional funding to complete the development and commercialization of our product candidates. If we are unable to raise this capital when needed, we may be forced to delay, reduce or eliminate our product development programs or other operations.

Since our inception, we have used substantial amounts of cash to fund our operations and expect our expenses to increase substantially during the next few years. The development of biopharmaceutical product candidates, especially immune-oncology product candidates, is capital intensive. As our product candidates enter and advance through preclinical studies and clinical trials, we will need substantial additional funds to expand our clinical, regulatory, quality and manufacturing capabilities. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to marketing, sales, manufacturing and distribution. Furthermore, we expect to incur additional costs associated with operating as a public company.

As of December 31, 2022 December 31, 2023, we had $142.6 million $143.2 million in cash and cash equivalents. Based upon our current operating plan, we estimate that our existing cash and cash equivalents will be sufficient to fund our operating expenses and capital expenditure requirements through into the third fourth quarter of 2024. 2025. However, our existing cash and cash equivalents may not be sufficient to fund any of our product candidates through regulatory approval, and we may will need to raise substantial additional capital to complete the development and commercialization of our product candidates.

We have based these estimates on assumptions that may prove to be incorrect or require adjustment as a result of business decisions, and we could utilize our available capital resources sooner than we currently expect. Our future capital requirements will depend on many factors, some of which are outside of our control, including:

- the initiation, design, progress, timing, costs and results of drug discovery, preclinical studies and clinical trials of our product candidates, and in particular the clinica for IO102-IO103;
- the number and characteristics of product candidates that we pursue;
- the number of clinical trials needed for regulatory approvals from the FDA, the European Commission (based on recommendation from the EMA), and any other reg authority;
- the length of our clinical trials, including, among other things, as a result of delays in enrollment, difficulties enrolling sufficient subjects or delays or difficulties in clinic site activations;
- increased costs associated with conducting our clinical trials, including, among other things, clinical trial site activations and patient enrollment;
- successfully complete completing ongoing pre-clinical studies and clinical trials;
- the outcome, timing and costs of seeking regulatory approvals from the FDA, the European Commission, and any other regulatory authority;

- the costs of manufacturing our product candidates, in particular for clinical trials in preparation for marketing approval and in preparation for commercialization;
- the costs of any third-party products used in our combination clinical trials that are not covered by such third party or other sources;
- the costs associated with hiring additional personnel and consultants as our preclinical, manufacturing and clinical activities increase;
- the receipt of marketing approval and revenue received from any commercial sales of any of our product candidates, if approved;
- the cost of commercialization activities for any of our product candidates, if approved, including marketing, sales, compliance and distribution costs;
- the emergence of competing therapies and other adverse market developments;
- the ability to establish and maintain strategic collaboration, licensing or other arrangements and the financial terms of such agreements;
- the extent to which we in-license or acquire other products and technologies;
- the amount and timing of any payments we may be required to make pursuant to our current or future license agreements;
- the costs involved in preparing, filing, prosecuting, maintaining, expanding, defending and enforcing patent claims, including litigation costs and the outcome o litigation;
- our need and ability to retain key management and hire scientific, technical, business, medical, and medical compliance personnel;
- our implementation of additional internal systems and infrastructure, including operational, financial, compliance and management information systems;
- or our costs associated with expanding our facilities or building out our laboratory space;
- the effects of the recent disruptions to and volatility in the credit and financial markets in the United States and worldwide from the COVID-19 pandemic, public emergencies, and geopolitical conflict (such as in Ukraine and the conflict between Russia and Ukraine; Middle East); and
- the costs of operating as a public company.

We will require additional capital to achieve our business objectives. Additional funds may not be available on a timely basis, on favorable terms, or at all, and such funds, if raised, may not be sufficient to enable us to continue to implement our long-term business strategy. Further, our ability to raise additional capital may be adversely impacted by potential worsening global economic conditions and the recent disruptions to and volatility in the credit and financial markets in the United States

and worldwide resulting from the ongoing COVID-19 pandemic. worldwide. If we are unable to raise sufficient additional capital, we could be forced to curtail our planned operations and the pursuit of our growth strategy.

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

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our operations through equity offerings, debt financings or other capital sources, including potentially grants, collaborations, licenses or other similar arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, our stockholders' ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of holders of our common stock. Additional debt financing, if available, may involve agreements that include covenants further limiting or restricting our ability to take specific actions, such as further limitations on our ability to incur additional debt, make capital expenditures or declare dividends.

If we raise funds through collaborations or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

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

Our development efforts are in the early stages. All of our product candidates are in clinical development or in preclinical development. if If we are unable to advance our product candidates through clinical development, obtain regulatory approval and ultimately commercialize our product candidates, or experience significant delays in doing so, our business will be materially harmed.

There is no assurance that clinical trials of IO102-IO103, or any other future clinical trials of our product candidates, will be successful or will generate positive clinical data and we may not receive marketing approval from the FDA, European Commission (based on recommendation from the EMA), or other regulatory authorities for any of our product candidates. We have limited experience submitting INDs to the FDA. IO112 is in initial clinical development, currently being studied in an investigator-initiated study. There can be no

assurance that the FDA will permit any of our future INDs, including any IND for IO112, to go into effect in a timely manner or at all. Without an IND for a product candidate, we will not be permitted to conduct clinical trials in the United States of such product candidate.

Biopharmaceutical development is a difficult, long, time-consuming, expensive and uncertain process, and delay or failure can occur at any stage of any of our clinical trials. For example, we have experienced longer than expected lead times in clinical trial site activation and patient enrollment in our clinical trials. Failure to obtain regulatory approval for our product candidates will prevent us from commercializing and marketing our product candidates. The success in the development of our product candidates will depend on many factors, including:

- timely and successful completion of preclinical studies;
- sufficiency of our financial and other resources to complete the necessary preclinical studies and clinical trials;
- obtaining and maintaining patent, trademark and trade secret protection and regulator regulatory exclusivity for our product candidates and otherwise protecting our ri our intellectual property portfolio;
- submission of INDs and CTAs for and receipt of allowance to proceed with our planned clinical trials or other future clinical trials;
- initiating, enrolling, and successfully completing clinical trials, including investigator-initiated clinical trials over which we have limited control;
- obtaining positive results from our preclinical studies and clinical trials that support a demonstration of efficacy, safety, and durability of effect for our product candidate
- receiving approvals for commercialization of our product candidates from applicable regulatory authorities;
- the outcome, timing and cost of meeting regulatory requirements established by the FDA, European Commission (based on recommendation from the EMA), and regulatory authorities;

- establishing sales, marketing and distribution capabilities and successfully launching commercial sales of our products, if and when approved, whether alone collaboration with others;
- maintaining a continued acceptable safety, tolerability and efficacy profile of any approved products;
- setting acceptable prices for our product and obtaining coverage and adequate reimbursement from third-party payors;

- acceptance of our products, if and when approved, by patients, the medical community and third-party payors;
- manufacturing our product candidates at an acceptable cost; and
- maintaining and growing an organization of scientists, medical and clinical professionals and business people professionals who can develop and commerciali products and technology.

Many of these factors are beyond our control, including the time needed to adequately complete clinical testing, the regulatory submission process and potential threats to our intellectual property rights. It is possible that none of our product candidates will ever obtain regulatory approval, even if we expend substantial time and resources seeking such approval. If we do not achieve one or more of these factors in a timely manner or at all, or any other factors impacting the successful development of biopharmaceutical products, we could experience significant delays or an inability to successfully develop our product candidates, which would materially harm our business.

The results of preclinical studies and early clinical trials are not always predictive of future results. Any product candidate that we advance in clinical trials, including IO102-IO103, may not achieve favorable results in later clinical trials, if any, or receive marketing approval.

The research and development of drugs and biological products is extremely risky. Only a small percentage of product candidates that enter the development process ever receive marketing approval. Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of the product candidates in humans. The outcome of clinical testing is uncertain. We may face unforeseen challenges in our product candidate development strategy, and we can provide no assurances that we will ultimately be successful in our current and future clinical trials or that our product candidates will be able to receive regulatory approval. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. For example, it is not uncommon for product candidates to exhibit unforeseen safety or efficacy issues when tested in humans despite promising results in preclinical animal models. In particular, while IO102-IO103 in combination with an anti-PD-1 monoclonal antibody has been investigated in a Phase 1/2 trial in 30 metastatic melanoma patients at Herlev University Hospital of Copenhagen, we do not know how IO102-IO103 will perform in our ongoing Phase 3 clinical trial combining IO102-IO103 with an anti-PD-1 monoclonal antibody in first line treatment of advanced melanoma patients, nor do we know how candidates in our ongoing Phase 2 basket trial, IOB-022, our ongoing Phase 2 basket trial, IOB-032 or in future clinical trials including the planned Phase 2 basket trial, IOB-032. will perform. Future results of preclinical and clinical testing of our product candidates are also less certain due to the novel and relatively untested nature of the approach of our T-win technology T-win® platform. In general, clinical trial failure may result from a multitude of factors including flaws in study design, dose selection, patient enrollment criteria and failure to demonstrate favorable safety or efficacy traits. As such, failure in clinical trials can occur at

any stage of testing. A number of companies in the biopharmaceutical industry, including immune-oncology companies, have suffered setbacks in the advancement of clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials.

Our product candidates are based on novel technologies that target the highly immunosuppressive tumor microenvironment, which makes it difficult to predict the results, timing, and cost of product candidate development and likelihood of obtaining regulatory approval.

We have concentrated our research and development efforts on product candidates using our T-win technology platform, and our future success depends on the successful development of this approach. Our product candidates target the tumor microenvironment which is highly immunosuppressive. We have not yet succeeded and may not succeed in demonstrating efficacy and safety for any product candidates based on our platform technologies in clinical trials or in obtaining marketing approval thereafter, and use of our platform technologies may not ever result in marketable products. We may also experience delays in developing a sustainable, reproducible and scalable manufacturing process or transferring that process to commercial partners or establishing our own commercial manufacturing capabilities, which may prevent us from completing our clinical trials or commercializing any products on a timely or profitable basis, if at all.

In addition, the clinical trial requirements of the FDA, and other regulatory authorities and the criteria these regulators use to determine the safety and efficacy of a product candidate vary substantially according to the type, complexity, novelty and intended use and market of the potential products. The regulatory approval process for novel product candidates such as ours can be less predictable, more expensive and longer than for other, better known or extensively studied pharmaceutical or other product candidates.

There is no assurance that the approaches offered by our products 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 proposed product candidates. Since our current product candidates and any future product candidates will represent novel approaches to treating various conditions, it may be difficult, in any event, to accurately estimate the potential revenues from these product candidates. Accordingly, we may spend significant capital trying to obtain approval for product candidates that have an uncertain commercial market. The market for any products that we successfully develop will also depend on the cost of the product. We do not yet have sufficient information to reliably estimate what it will cost to commercially manufacture our current product candidates, and the actual cost to manufacture these products could materially and adversely affect the commercial viability of these products. 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 products, we will not become profitable, which would materially and adversely affect the value of our common stock.

The immuno-oncology oncology industry is also rapidly developing, and our competitors may introduce new technologies improving the immune response to cancer that render our technologies obsolete or less attractive. New technology could emerge at any point in the development cycle of our product candidates.

We are investigating IO102-IO103 in clinical trials in melanoma and other solid tumors, and our third product candidate, IO112, targets an immune resistance pathway known as Arginase 1 which is highly expressed in solid cancer indications. If our product candidates do not show any functionality in the solid tumor microenvironment, our development plans, financial position, results of operations and prospects may be materially adversely affected.

While we plan to develop product candidates for use in solid tumors, including IO102-IO103 and IO112, our product candidates may not show any functionality in the solid tumor microenvironment. The cellular environment in which solid tumor cells thrive is generally hostile to T cells due to factors such as the presence of immunosuppressive cells, humoral factors and limited access to nutrients. Our product candidates may not be able to access the solid tumor, and even if they do, they may not be able to exert anti-tumor effects in a hostile tumor microenvironment. In addition, the safety profile of our product candidates may differ in a solid tumor setting. As a result, our product candidates may not demonstrate efficacy in solid tumors. If we are unable to make our product candidates function in solid tumors, our development plans, financial position, results of operations and prospects may be materially adversely affected.

We have experienced, and may in the future experience delays, or difficulties in clinical trial site activations and the enrollment and/or retention of patients in clinical trials, which could delay or prevent our receipt of necessary regulatory approvals.

Successful and timely completion of clinical trials will require that we enroll a sufficient number of patients. Patient enrollment, which is an important factor in the timing of clinical trials, is affected by many factors, including clinical trial site activation, the size and nature of the patient population and competition for patients eligible for our clinical trials with competitors which may have ongoing clinical trials for product candidates that are under development to treat the same indications as one or more of our product candidates, or approved products for the conditions for which we are developing our product candidates.

Trials may be subject to delays as a result of patient enrollment taking longer than anticipated or patient withdrawal. As a result of the on-going COVID-19 pandemic public health emergencies and continuing resource constraints on CROs, us, prospective clinical trial sites and others, we are currently experiencing may experience longer than expected lead times in clinical trial site activation and patient enrollment in our clinical trials. Furthermore, enrollment for our Phase 3 potentially registrational trial clinical trials may take longer than anticipated due to other monotherapies and combination therapies being investigated in the first-line setting at this time. We may not be able to initiate or continue clinical trials

for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required to adequately power our studies in order to draw meaningful conclusions from them or as may be required by the FDA, EMA, European Commission (based on recommendation from the EMA), or comparable foreign regulatory authorities. We cannot predict how successful we will be at enrolling subjects in future clinical trials. Subject enrollment is affected by other factors including:

- the pace of clinical trial site activation;
- the severity and difficulty of diagnosing the disease under investigation;

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- the eligibility and exclusion criteria for the trial in question;
- the size of the patient population and process for identifying patients;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- the design of the trial protocol;

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- the perceived risks and benefits of the product candidate in the trial, including relating to cell therapy approaches;
- the availability of competing commercially available therapies and other competing therapeutic candidates' clinical trials for the disease or condition under investi including for melanoma and other cancers in a first-line setting;
- the willingness of patients to be enrolled in our clinical trials;
- the efforts to facilitate timely enrollment in clinical trials;
- potential disruptions caused by the COVID-19 pandemic, including difficulties in initiating clinical sites, enrolling and retaining participants, diversion of healthcare res away from clinical trials, travel or quarantine policies that may be implemented, and other factors;
- the patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment; and
- the proximity and availability of clinical trial sites for prospective patients.

The FDA may also modify or enhance clinical trial requirements, which may affect enrollment and retention of patients. In August 2023, the FDA published a guidance document, "Informed Consent, Guidance for IRBs, Clinical Investigators, and Sponsors," which supersedes past guidance and finalizes draft guidance on informed consent. The FDA's new guidance presents evolving requirements for informed consent which may affect recruitment and retention of patients in clinical trials. Effects on recruitment and retention of patients may hinder or delay a clinical trial, which may increase costs and delay clinical programs.

Our inability to enroll a sufficient number of patients for clinical trials would result in significant delays and could require us to abandon one or more clinical trials altogether. Enrollment delays in these clinical trials may result in increased development costs for our product candidates, which would cause the value of our company to decline and limit our ability to obtain additional financing. Furthermore, we expect to rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials and we will have limited influence over their performance.

Interim "top-line" and preliminary results 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 publish interim top-line or preliminary results from our clinical trials. Interim results 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. Preliminary or top-line results also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim and preliminary data that we report may differ from future results of the same trials, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated, and should be viewed with caution until the final data are available. Differences between preliminary or interim data and final data could significantly harm our business prospects and may cause the trading price of our common stock to fluctuate significantly.

The regulatory approval processes of the FDA, European Commission (based on recommendation from the EMA), and comparable foreign authorities are lengthy, time consuming and inherently unpredictable. if If we are not able to obtain required regulatory approval for our product candidates, our business will be substantially harmed.

The time required to obtain approval or other marketing authorizations by the FDA, European Commission (based on recommendation from the EMA), and comparable foreign regulatory authorities is unpredictable, and it typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, and 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. We have not obtained regulatory approval for any product candidate, and it is possible that we may never obtain regulatory approval for any product candidates we may seek to develop in the future. Neither we nor any current or future collaborator is permitted to market any drug product candidates in the United States until we receive regulatory approval of a BLA from the FDA, and we cannot market it in the EU until we receive a MAA from the European Commission (based on recommendation from the EMA), or in the UK until we receive regulatory approval from the Medicines and Healthcare Products Regulatory Agency (MHRA) or other required regulatory approval in other countries. To date, we have had only limited discussions with the FDA and EMA regarding clinical development programs or regulatory approval for any product candidate within the United

States and EU, respectively. In addition, we have had no discussions with other comparable foreign authorities regarding clinical development programs or regulatory approval for any product candidate outside of those jurisdictions.

Prior to obtaining approval to commercialize any drug product candidate in the United States or abroad, we must demonstrate with evidence from well-controlled clinical trials, and to the satisfaction of the FDA, European Commission (based on recommendation from the EMA), or other foreign regulatory authorities, that such product candidates are safe and effective for their intended uses. Results from preclinical studies and clinical trials can be interpreted in different ways. Even if we believe the preclinical or clinical data for our product candidates are promising, such data may not be sufficient to support approval by the FDA, the European Commission (based on recommendations from the EMA), and other comparable foreign regulatory authorities. The FDA or European Commission (based on recommendations from the EMA) may also require us to conduct additional preclinical studies or clinical trials for our product candidates either prior to or after approval, or it may object to elements of our clinical development programs.

Our product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA, EMA, or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials, or with our interpretation of clinic results;
- we may be unable to demonstrate to the satisfaction of the FDA, EMA, or comparable foreign regulatory authorities that a product candidate is safe and effective proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by the FDA, European Commission (based on recommendation from the EM comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA, European Commission (based on recommendation from the EMA), or comparable foreign regulatory authorities may fail to approve the manufacturing pro or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA, European Commission, EMA, or comparable foreign authorities may significantly change in a manner rendering our data insufficient for approval.

Of the large number of products in development, only a small percentage successfully complete the FDA, European Commission (based on recommendation from the EMA), or foreign regulatory approval processes and are commercialized. The lengthy approval and marketing authorization process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval and marketing authorization to market our product candidates, which would significantly harm our business, financial condition, results of operations and prospects.

In the EU, the EMA's Committee for Advanced Therapies (CAT) is responsible for assessing the quality, safety, and efficacy of advanced therapy medicinal products (ATMPs). ATMPs include gene therapy medicines, somatic-cell therapy medicines and tissue-engineered medicines. The role of the CAT is to prepare a draft opinion on an application for marketing authorization for a gene therapy medicinal candidate that is submitted to EMA's Committee for Medicinal Products for Human Use (CHMP) for final adoption. In the EU, the development and evaluation of ATMPs follow relevant EU guidelines. European Commission or EMA may issue new guidelines concerning the development and marketing authorization for ATMPs and require that we comply with these new guidelines.

We have invested a significant portion of our time and financial resources in the development of our clinical and preclinical product candidates. Our business is dependent on our ability to successfully complete preclinical and clinical development of, obtain regulatory approval for, and, if approved, successfully commercialize IO102-IO103, IO112 and any future product candidates in a timely manner.

Even if we eventually complete clinical testing and receive approval of a BLA or other comparable foreign marketing application for IO102-IO103, IO112 or any future product candidates, the FDA, European Commission (based on recommendation from the EMA) or other comparable foreign regulatory authorities may grant approval or other marketing authorization contingent on the performance of costly additional clinical trials, including post-marketing clinical trials. The FDA, European Commission (based on recommendations from the EMA) or other comparable foreign regulatory authorities may also approve or authorize for marketing a product candidate for a more limited indication or patient population than we originally request, and the FDA, European Commission (based on recommendations from the EMA) or other comparable foreign regulatory authorities

may not approve or authorize the labeling that we believe is necessary or desirable for the successful commercialization of a product candidate. Any delay in obtaining, or inability to obtain, applicable regulatory

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approval or other marketing authorization would delay or prevent commercialization of that product candidate and would materially adversely impact our business and prospects.

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In addition, the FDA, European Commission (based on recommendations from the EMA), or other comparable foreign regulatory authorities and regulatory review committees described above may change their policies, issue additional regulations or revise existing regulations, or take other actions, which may prevent or delay approval of our future products under development on a timely basis. Such policy or regulatory changes could impose additional requirements upon us that could delay our ability to obtain approvals, increase the costs of compliance or restrict our ability to maintain any marketing authorizations we may have obtained.

Our preclinical studies and clinical trials may fail to demonstrate the safety and efficacy of our product candidates, or serious adverse or unacceptable side effects may be identified during the development of our product candidates, which could prevent, delay or limit the scope of regulatory approval of our product candidates, limit their commercialization, increase our costs or necessitate the abandonment or limitation of the development of some of our product candidates.

To obtain the requisite regulatory approvals for the commercial sale of our product candidates, we must demonstrate through lengthy, complex and expensive preclinical testing and clinical trials that our product candidates are safe and effective for use in each target indication. These trials are expensive and time consuming, and their outcomes are inherently uncertain. Failures can occur at any time during the development process. Preclinical studies and clinical trials often fail to demonstrate safety or efficacy of the product candidate studied for the target indication, and most product candidates that begin clinical trials are never approved.

We may fail to demonstrate with evidence from adequate and well-controlled trials, and to the satisfaction of the FDA, European Commission (based on recommendation from the EMA), or comparable foreign regulatory authorities, that our product candidates are safe and effective for their intended uses.

Possible adverse reactions and adverse side effects that could occur with immuno-oncology treatments can be severe. For example, we have reported to FDA some serious and unexpected suspected adverse reactions from the IO102-112 IOB-012 trial to FDA, which involved pulmonary tuberculosis, enterocolitis, hypovolemic shock, and diabetic ketoacidosis. Depending As part of routine safety monitoring and pharmacovigilance evaluation on ongoing and planned trials, we continue to review data and perform additional assessments, depending on an evaluation of the available data, we may decide or be required to perform additional preclinical studies or to halt or delay further clinical development of our product candidates or to limit their development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe, or more acceptable from a risk-benefit perspective, which may limit the commercial expectations for the product candidate, if approved.

Our clinical trials could also be suspended or terminated and the FDA, EMA, European Commission (based on recommendation from the EMA), or comparable foreign regulatory authorities could order us to cease further development of, or deny approval of, our product candidates for any or all targeted indications. Even if this does not occur, reports of serious reactions could affect patient recruitment or the ability of enrolled patients to complete the trial. Moreover, if we elect, or are required, to not initiate, delay, suspend or terminate any future clinical trial of any of our product candidates, the commercial prospects of such product candidates may be harmed and our ability to generate product revenues from any of these product candidates may be delayed or eliminated. Any of these occurrences may harm our ability to develop other product candidates, and may harm our business, financial condition and prospects significantly.

If our product candidates are associated with side effects in clinical trials or have characteristics that are unexpected, we may need to abandon their development or limit development to more narrow uses in which the side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. The FDA, EMA, European Commission (based on recommendation from the EMA), an institutional review board (IRB) or ethics committee (EC), which are local institutional boards or committees, as applicable, that review, approve and oversee basic and clinical research conducted as the institution participating in the clinical trial, or comparable foreign regulatory authorities, may also require that we suspend, discontinue, or limit our clinical trials based on safety information, or that we conduct additional animal or human studies regarding the safety and efficacy of our product candidates which we have not planned or anticipated. Such findings could further result in regulatory authorities failing to provide marketing authorization for our product candidates or limiting the scope of the approved indication, if approved. Many product candidates that initially showed promise in early stage testing have later been found to cause side effects that prevented further development of the product candidate.

As an organization, we have never conducted pivotal clinical trials, and we may be unable to do so for any product candidates we may develop.

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We will need to successfully complete clinical trials meeting requirements for approval of the FDA or comparable foreign regulatory authorities, known as pivotal trials, to market IO102-IO103, IO112, IO170 or any future product candidate. Carrying out Conducting and successfully completing pivotal clinical trials is a complicated process. As an organization, Consequently, we have not previously conducted any later stage may be unable to successfully and efficiently execute and complete necessary clinical trials in a way that leads to BLA submission and approval of IO102-IO103, IO112, IO170 or pivotal clinical trials. future product candidates. In order to do so, we will need to expand our clinical development and regulatory capabilities, and we may be unable to recruit and train qualified personnel. We also expect to continue to rely on third parties to conduct our pivotal clinical trials. Consequently, we may be unable to successfully and efficiently execute and complete necessary clinical trials in a way that leads to BLA submission and approval of IO102-IO103, IO112, or future product candidates. We also may require more time and incur greater costs than our competitors and may not succeed in obtaining regulatory approvals of product candidates that we develop. Failure to commence or complete, or delays in, our planned clinical trials, could prevent us from or delay us in commercializing our product candidates.

Some data for product candidates comes from clinical trials conducted outside the United States, EU and the UK, and the FDA, EMA, European Commission (based on recommendation from the EMA), or comparable foreign regulatory authorities may not accept data from such trials.

Although we believe that the patient population in the Phase 1/2 trial with IO102-IO103 in combination with an anti-PD-1 monoclonal antibody in 30 metastatic melanoma patients is representative of the population for which we intend to label our IO102-103 product candidate in the United States, the trial was conducted in Europe, our ongoing IOB-013/KN-D18 and IOB-022 trials include sites outside of the United States, and we may conduct additional trials in the future outside of the United States, Europe and the UK. United Kingdom. The acceptance of data from clinical trials conducted outside the United States or another jurisdiction by the FDA may be subject to certain conditions or may not be accepted at all. Similarly, the EMA, European Commission (based on recommendation from the EMA), and other equivalent foreign regulatory authorities may not accept data from trials conducted outside their jurisdiction. In cases where data from foreign clinical trials are intended to serve as the basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (1) the data are applicable to the U.S. population and U.S. medical practice; and (2) the trials were performed by clinical investigators of recognized competence and pursuant to good clinical practice (GCP) regulations; and (3) the data may be considered valid without the need for an on-site inspection by the FDA, or if the FDA considers such inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. In general, the patient population for any clinical trials conducted outside the United States must be representative of the population for whom we intend to label the product candidate in the United States. Additionally, the FDA's clinical trial requirements, including sufficient size of patient populations and statistical powering, must be met. Many foreign regulatory authorities have similar approval requirements for clinical trials. In addition, such trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA, EMA, European Commission (based on recommendation from the EMA), or any comparable foreign regulatory authority will accept data from trials conducted outside of the applicable jurisdiction. If the FDA, EMA, European Commission (based on recommendation from the EMA), or any comparable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which could be costly and time-consuming, and which may result in product candidates that we may develop not receiving approval for commercialization in the applicable jurisdiction.

Breakthrough therapy designation by the FDA for any product candidate may not lead to a faster development or regulatory review or approval process, and it does not increase the likelihood that the product candidate will receive marketing approval approval.

IO102-IO103 combined with an anti-PD-1 monoclonal antibody in first line metastatic melanoma patients has been granted BTD from the FDA. We may also, in the future, apply for BTD, or the equivalent thereof in foreign jurisdictions (where available), for our product candidates or programs. A breakthrough therapy is defined as a product candidate that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the product candidate may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For product candidates that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Product candidates designated as breakthrough therapies by the FDA are also eligible for priority review if supported by clinical data at the time of the submission of the BLA.

BTD is within the discretion of the FDA. Accordingly, even if we believe that one of our product candidates meets the criteria for BTD, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a breakthrough therapy designation for a product candidate, including the breakthrough therapy designation of IO102-IO103 combined with an anti-PD-1 monoclonal antibody in first line metastatic melanoma patients, may not result in a faster development process, review or approval compared to product candidates considered for approval under conventional FDA procedures and it would not assure ultimate approval by the FDA. In addition, even after a product

candidate qualifies as a breakthrough therapy, the FDA may later decide that the product candidate no longer meets the conditions for qualification or it may decide that the time period for FDA review or approval will not be shortened.

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We may submit a BLA for our product candidates under the Accelerated Approval Pathway. If we are unable to obtain licensure of our biological candidates through the Accelerated Approval Program Pathway in the United States, we may be required to conduct additional nonclinical and clinical studies and trials beyond those that we currently contemplate, which could increase the expense of obtaining, reduce the likelihood of obtaining and/or delay the timing of obtaining, necessary marketing approval. Even if we receive licensure from the FDA through the Accelerated Approval Program, if any required confirmatory post-marketing trial does not verify clinical benefit, or if we do not comply with rigorous post-marketing requirements, the FDA may seek to withdraw the approval.

We may seek approval under the Accelerated Approval pathway Pathway for our IO102-IO103, IO112 or any other product candidates. For any approval to market a product, we must provide the FDA and foreign regulatory authorities with clinical data that adequately demonstrate the safety, efficacy, purity and potency of the product for the indication applied for in the BLA, or other respective regulatory filings. The Accelerated Approval Program Pathway is one of several approaches used by the FDA to make prescription drugs and biologics more rapidly available for the treatment of serious or life-threatening diseases. Section 506(c) of the FDCA provides that the FDA may grant accelerated approval to "a product for a serious or life-threatening condition upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, 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." Approval through the Accelerated Approval Program Pathway is typically subject, however, to the requirement that the applicant conduct additional post-marketing clinical trials to verify and describe the product's clinical benefit. Typically, clinical benefit is verified when post-marketing clinical trials show that the product provides a clinically meaningful positive therapeutic effect, that is, an effect on how a patient feels, functions, or survives. If such confirmatory post-marketing trial fails to confirm the product's clinical profile or risks and benefits, the FDA may withdraw its approval of the product.

The FDA has broad discretion with regard to approval through the Accelerated Approval Program, Pathway, and even if we believe that the Accelerated Approval Program Pathway is appropriate for our product candidates, we cannot assure you that the FDA will ultimately agree. Furthermore, even if we do obtain approval through the Accelerated Approval Program, Pathway, we may not experience a faster development process, review or approval compared to conventional FDA procedures.

Even if we receive approval for one or more of our product candidates through the Accelerated Approval Program, Pathway, we will be subject to rigorous post-marketing requirements, possibly including the completion of one or more confirmatory post- marketing trials as the FDA may require, to verify the clinical benefit of the product, and submission to the FDA of all promotional materials prior to their dissemination. The FDA could seek to withdraw the approval for multiple reasons, including if we fail to conduct any required confirmatory post-marketing trial with due diligence, our confirmatory post-marketing trial does not confirm the predicted clinical benefit, other evidence shows that the product is not safe, effective, pure or potent under the conditions of use, or we disseminate promotional materials that are found by the FDA to be false and misleading.

Moreover, Congress has recently enacted changes to the Accelerated Approval Program Pathway that could impact our ability to obtain Accelerated Approval, or increase the burdens associated with post-marketing requirements in the event we do obtain Accelerated Approval. In particular, the FDA must specify certain conditions for required post-approval studies for products that receive Accelerated Approval, which may include enrollment targets and milestones, including the target date for study completion, by the time the biologic is licensed. FDA may also require post-approval studies to be underway at the time of Accelerated Approval or within a specified time period following Accelerated Approval for such biologics.

Any delay in obtaining, or inability to obtain, approval or licensure through the Accelerated Approval Program, Pathway, or any issues in maintaining approval or licensure granted under the Accelerated Approval Program, Pathway, would delay or prevent commercialization of our products, and could materially adversely affect our business, financial condition, results of operations, cash flows and prospects.

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Even if we receive regulatory approval for any of our product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense. Additionally, our product candidates, if approved, could be subject to post-market study requirements, marketing and labeling restrictions, and even recall or market withdrawal if unanticipated safety issues are discovered following approval. In addition, we may be subject to penalties or other enforcement action if we fail to comply with regulatory requirements.

If the FDA, the European Commission (based on recommendation from the EMA), or a comparable foreign regulatory authority approves any of our product candidates, the manufacturing processes, labeling, packaging, distribution, storage,

advertising, promotion, import, export, recordkeeping, monitoring, and reporting for our product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, establishment registration and listing, as well as continued compliance with current Good Manufacturing Practice requirements (cGMPs) and GCP requirements for any clinical trials that we conduct post-approval. 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 the conditions of approval, or contain requirements for potentially costly post-marketing studies, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the product.

The FDA may require a REMS in order to approve our product candidates, which could entail requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- revision to the labeling, including limitations on approved uses or the addition of additional warnings, contraindications or other safety information, including boxed wa
- 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;
- fines, warning letters or other regulatory enforcement action;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us;
- product seizure or detention, or refusal to permit the import or export of products; and
- injunctions or the imposition of civil or criminal penalties;

In the EU, the European Commission (based on recommendation from the EMA) may will require an equivalent risk management plan (RMP). The FDA's, European Commission's, EMA's, and other comparable foreign regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

We anticipate that our current product candidates and any future product candidates will be used in combination with third-party drugs or biologics, some of which are still in development, and we have limited or no control over the supply, regulatory status, or regulatory approval of such drugs or biologics.

Our T-win technology T-win® platform targets both immune suppressive host and tumor cells in the TME initiating a dynamic process of activating the host immune system, which response can be further exploited by concurrent or subsequent therapies as checkpoint inhibitors such as the dominant PD-1 monoclonal antibodies, pembrolizumab and nivolumab. Accordingly, it is expected that our product candidates, if approved, would be used in combination with third-party drugs or biologics. For example, IO102-IO103 in combination with an anti-PD-1 monoclonal antibody was investigated in a Phase 1/2 trial in 30 metastatic melanoma patients at Herlev University Hospital of Copenhagen, and we are conducting a Phase 3 clinical trial, the IOB-013/KN-D18 trial, combining IO102-IO103 with an pembrolizumab in first line advanced melanoma patients. Our ability to develop and ultimately commercialize our current product candidates and any future product candidates used in combination with pembrolizumab, nivolumab, or any other checkpoint inhibitor immunotherapies will depend on our ability to access such drugs or biologics on commercially reasonable terms for the clinical trials and their availability for use with the commercialized product, if approved. We cannot be certain that current or potential future commercial relationships will provide us with a steady supply of such drugs or biologics on commercially reasonable terms or at all.

Any failure to maintain or enter into new successful commercial relationships, or the expense of purchasing checkpoint inhibitor immunotherapies or other comparator therapies in the market, may delay our development timelines, increase our costs and jeopardize our ability to develop our current product candidates and any future product candidates as commercially viable therapies. If any of these occur, our business, financial condition, results of operations, stock price and prospects may be materially harmed.

Moreover, the development of product candidates for use in combination with another product or product candidate may present challenges that are not faced for single agent product candidates. We are currently developing IO102-IO103 and IO112 and may develop other future product candidates for use in combination with checkpoint inhibitors and may develop IO102-IO103 and IO112, or any future product candidates for use with other therapies. The FDA, EMA, or comparable foreign regulatory authorities 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. It is possible that the results of such trials could show that any positive previous trial results are attributable to the combination therapy and not our current product candidates and any future product candidates. It is

also possible that trial results for our product candidates may differ significantly if our product candidates are investigated with different combination therapies in different trials - for example, if we were to investigate our product candidates with one anti-PD-1 monoclonal antibody in one trial and a different anti-PD-1 monoclonal antibody in another. Moreover, following product approval, the FDA, EMA, or comparable foreign regulatory authorities may require that products used in conjunction with each other be cross labeled for combined use. To the extent that we do not have rights to the other product, this may require us to work with a third party to satisfy such a requirement. Moreover, developments related to the other product may impact our clinical trials for the combination as well as our commercial prospects should we receive marketing approval. Such developments may include changes to the other product's safety or efficacy profile, changes to the availability of the approved product, quality, manufacturing and supply issues, and changes to the standard of care.

In the event that any of our collaborators or suppliers cannot continue to supply their products on commercially reasonable terms, we would need to identify alternatives for accessing such checkpoint inhibitor immunotherapies. Additionally, should the supply of products from any collaborator or supplier be interrupted, delayed or otherwise be unavailable to us, our clinical trials may be delayed. In the event we are unable to source an alternative supply, or are unable to do so on commercially reasonable terms, our business, financial condition, results of operations, stock price and prospects may be materially harmed.

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

Because we have limited financial and managerial resources, we must prioritize our research programs and will need to focus our discovery and development on select product candidates and indications. Correctly prioritizing our research and development activities is particularly important for us due to the breadth of potential product candidates and indications that we believe could be pursued using our platform technologies. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may also relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

Our success largely depends on the success of our limited number of product candidates. If any of these candidates fail in clinical trials or are not approved for commercialization, our ability to generate revenue and achieve profitability could be impacted.

We expect initially to focus on the development of our lead dual epitope IO102-IO103. We also expect to continue to develop our third other product candidate, IO112. candidates, IO112 and IO170. A key part of our strategy, however, is to continue to pursue clinical development of additional product candidates utilizing our T-win technology T-win® platform. Developing, obtaining marketing approval for, and commercializing any future product candidates will require substantial additional funding beyond the net proceeds of our IPO and will be subject to the risks of failure inherent in drug product development. We cannot assure you that we will be able to successfully advance any future product candidates through the development process.

Even if we obtain approval from the FDA, European Commission (based on recommendation from the EMA) or comparable foreign regulatory authorities to market any future product candidates for the treatment of tumors, we cannot assure that any such product candidates will be successfully commercialized, widely accepted in the marketplace, or more effective than other commercially available alternatives. If we are unable to successfully develop and commercialize additional product candidates our commercial opportunity may be limited and our business, financial condition, results of operations, stock price and prospects may be materially harmed.

Difficulty in enrolling patients could delay or prevent clinical trials of our current product candidates and any future product candidates. We may find it difficult to enroll patients in our ongoing clinical trials or any subsequent trials we may

conduct and our receipt of necessary regulatory approvals could be delayed or prevented. For example, we have experienced longer than expected lead times in clinical trial site activation and patient enrollment in our clinical trials.

Identifying and qualifying patients to participate in clinical studies of our current product candidates and any future product candidates is critical to our success. The timing of completion of our clinical trials depends in part on the speed at which we can recruit patients to participate in testing our current product candidates and any future product candidates, and we may experience delays in our clinical trials if we encounter difficulties in enrollment or patient retention due to other unforeseen factors. We may not be able to initiate or continue clinical trials for our current product candidates and any future product candidates if we are unable to locate and enroll and retain a sufficient number of eligible patients to participate in these trials as required by the FDA, EMA, or comparable foreign regulatory authorities outside the United States. For example, the COVID-19 pandemic has impacted and may continue to impact, our ability to initiate clinical sites and recruit, enroll and retain patients, or similar public health emergencies may divert healthcare resources

away from clinical trials. In addition, some of our competitors have ongoing clinical trials for product candidates that treat the same indications as our current product candidates, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' product candidates or future product candidates.

In addition to the competitive trial environment, the eligibility criteria of our planned clinical trials will further limit the pool of available study participants as we will require that patients have specific characteristics that we can measure to assure their cancer is either severe enough or not too advanced to include them in a study. Additionally, the process of finding patients may prove costly. We also may not be able to identify, recruit and enroll a sufficient number of patients to complete our clinical studies because of the perceived risks and benefits of the product candidates under study, the availability and efficacy of competing therapies and clinical trials, the proximity and availability of clinical trial sites for prospective patients, and the patient referral practices of physicians. If patients are unwilling to participate in our studies for any reason, the timeline for recruiting patients, conducting studies and obtaining regulatory approval of potential products may be delayed.

The enrollment of patients further depends on many factors, including:

- the size of the patient population and process for identifying patients;
- the eligibility criteria for the clinical trial in question;
- the availability of an appropriate screening test, as necessary;
- the perceived risks and benefits of the product candidate under study;
- the efforts to facilitate timely enrollment in clinical trials;
- the proximity and availability of clinical trial sites for prospective patients;
- the design of the clinical trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- our ability to obtain and maintain patient consents;
- reporting of the preliminary results of any of our clinical trials; and
- the risk that patients enrolled in clinical trials will drop out of the clinical trials before clinical trial completion.

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In addition, our clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as our current product candidates and any future product candidates, and this competition will may reduce the number and types of patients available to us because some patients who might have opted to enroll in our clinical trials may instead opt to enroll in a clinical trial being conducted by one of our competitors. Since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will may reduce the number of patients who are available for our clinical trials at such clinical trial sites. Furthermore, even if we are able to enroll a sufficient number of patients for our clinical trials, we may have difficulty maintaining enrollment of such patients in our clinical trials.

If we experience delays in the completion of, or termination of, any clinical trial of our current product candidates and any future product candidates, the commercial prospects of our current product candidates and any future product candidates will be harmed, and our ability to generate product revenue from such product candidates could be delayed or prevented.

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Our future growth depends, in part, on our ability to penetrate multiple markets in which we would be subject to additional regulatory burdens and other risks and uncertainties.

Our future profitability will depend, in part, on our ability to commercialize our product candidates, if approved, in markets in the United States, Europe, the UK, United Kingdom, and other countries where we maintain commercialization rights. As we begin to commercialize our product candidates, if approved, in multiple markets, we are subject to additional risks and uncertainties, including:

- foreign currency exchange rate fluctuations and currency controls;
- economic weakness, including inflation, or political instability in particular economies and markets;
- uncertainties related to Brexit, including potential impacts on costs, exchange rates, flow of goods, manufacturing and operations;
- potentially adverse and/or unexpected tax consequences, including penalties due to the failure of tax planning or due to the challenge by tax authorities on the b transfer pricing and liabilities imposed from inconsistent enforcement;
- the burden of complying with complex and changing regulatory, tax, accounting and legal requirements, many of which vary between countries;
- different medical practices and customs in multiple countries affecting acceptance of drugs in the marketplace;

- differing payor reimbursement regimes, governmental payors or patient self-pay systems and price controls;
- tariffs, trade barriers, import or export licensing requirements or other restrictive actions;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- workforce uncertainty in countries where labor unrest is common;
- reduced or loss of protection of intellectual property rights in some foreign countries, and related prevalence of generic alternatives to therapeutics; and
- becoming subject to the different, complex and changing laws, regulations and court systems of multiple jurisdictions and compliance with a wide variety of foreign treaties and regulations.

These and other risks associated with international operations may adversely affect our ability to attain or maintain profitable operations. Future sales of our products or our product candidates, if they are approved, will be dependent on purchasing decisions of and reimbursement from government health administration authorities, distributors and other organizations. As a result of adverse conditions affecting the global economy and credit and financial markets, including disruptions due to political instability, geopolitical conflict or otherwise, these organizations may defer purchases, may be unable to satisfy their purchasing or reimbursement obligations, or may affect milestone payments or royalties for our products or any of our product candidates that are approved for commercialization in the future. Should any of these risks materialize, this could have a material adverse effect on our business, prospects, financial condition and results of operations.

Risks Related to Manufacturing and Commercialization

The manufacture of our product candidates is complex and we may encounter difficulties in production, particularly with respect to process development or scaling-out scale-up of our manufacturing capabilities. If we encounter such difficulties, our ability to provide supply of our product candidates for clinical trials or our products for patients, if approved, could be delayed or stopped.

We have not yet manufactured or processed our product candidates on a commercial scale and may not be able to do so for any of our product candidates. We may encounter difficulties in production, particularly in scaling up or out, validating the production process, and assuring high reliability of the manufacturing process. These problems may include delays or break-downs in logistics and shipping, difficulties with production costs and yields, quality control, and product testing, operator error, lack of availability of qualified personnel, as well as failure to comply with strictly enforced federal, state and foreign regulations.

Furthermore, if contaminations are discovered in our supply of product candidates or in the manufacturing facilities, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. We cannot assure you that any of these or other issues relating to the manufacture of our product candidates will not occur in the future. Any delay or interruption in the supply of clinical trial supplies could delay the completion of clinical trials, increase

the costs associated with maintaining clinical trial programs and, depending upon the period of delay, require us to begin new clinical trials at additional expense or terminate clinical trials completely.

Manufacturing facilities also require commissioning and validation activities to demonstrate that they operate as designed, and are subject to government inspections by the FDA, EU Member States coordinated (coordinated by the EMA, EMA) and other comparable foreign regulatory authorities. If we are unable to reliably produce products to specifications acceptable to the regulatory authorities, we may not obtain or maintain the approvals we need to manufacture our products. Further, manufacturing facilities may fail to pass government inspections prior to or after the commercial launch of our product candidates, which would cause significant delays and additional costs required to remediate any deficiencies identified by the regulatory authorities. Any of these challenges could delay completion of clinical trials, require bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidate, impair commercialization efforts, increase our cost of goods, and have an adverse effect on our business, financial condition, results of operations and growth prospects.

Changes in product candidate manufacturing or formulation may result in additional costs or delay.

As product candidates are developed through preclinical studies to later-stage clinical trials towards 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 processes and results. Any of these changes could cause our current product candidates or any future product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered materials. Such changes may also require additional testing, or notification to, or approval by the FDA, European Commission, EMA, or a comparable foreign regulatory authority. This could delay completion of clinical trials, require the conduct of bridging clinical trials or studies, require the repetition of one or more clinical trials, increase

clinical trial costs, delay approval of our current product candidates and any future product candidates and/or jeopardize our ability to commence product sales and generate revenue.

Even if any of our product candidates receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.

Even if we obtain marketing approvals from the FDA, European Commission (based on recommendation from the EMA), or other comparable foreign regulatory agencies and are able to initiate commercialization of our clinical-stage product candidates or any other product candidates we develop, the product candidate may not achieve market acceptance among physicians, patients, hospitals, including pharmacy directors, cancer treatment centers, and third-party payors and, ultimately, may not be commercially successful. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the clinical indications for which our product candidates are approved;
- physicians, hospitals, cancer treatment centers, and patients considering our product candidates as a safe and effective treatment;
- the potential and perceived advantages of our product candidates over alternative treatments;
- the prevalence and severity of any side effects;
- product labeling or product insert requirements of the FDA, European Commission, EMA, or other comparable foreign regulatory authorities;
- limitations or warnings contained in the labeling approved by the FDA, European Commission, EMA, or other comparable foreign regulatory authorities;

- the timing of market introduction of our product candidates as well as competitive products;
- the cost of treatment in relation to alternative treatments;
- the amount of upfront costs or training required for physicians to administer our product candidates;
- the availability of coverage from, adequate reimbursement from, and our ability to negotiate pricing with, third-party payors and government authorities;
- the willingness of patients to pay out-of-pocket in the absence of comprehensive coverage and reimbursement by third-party payors and government authorities;

- relative convenience and ease of administration, including as compared to alternative treatments and competitive therapies; and
- the effectiveness of our sales and marketing efforts and distribution support.

Our efforts to educate physicians, patients, third-party payors and others in the medical community on the benefits of our product candidates, if approved, may require significant resources and may never be successful. Such efforts may require more resources than are typically required due to the complexity and uniqueness of our product candidates. Because we expect sales of our product candidates, if approved, to generate substantially all of our product revenue for the foreseeable future, the failure of our product candidates to find market acceptance would harm our business and could require us to seek additional financing. Even if our product candidates, if approved, achieve market acceptance, we may not be able to maintain that market acceptance over time if new products or technologies are introduced that are more favorably received than our products, are more cost effective or render our products obsolete.

We may not be able to successfully commercialize our product candidates, if approved, due to unfavorable pricing regulations or third-party coverage and reimbursement policies, which could make it difficult for us to sell our product candidates profitablyprofitably.

Obtaining coverage and reimbursement approval for a product from a government or other third-party payor is a time-consuming and costly process, with uncertain results, that could require us to provide supporting scientific, clinical and cost effectiveness data for the use of our products to the payor. There may be significant delays in obtaining such coverage and reimbursement for newly approved products, and coverage may not be available, or may be more limited than the purposes for which the product is approved by the FDA or other comparable foreign regulatory authorities. Moreover, eligibility for coverage and reimbursement does not imply that a product will be paid for in all cases or at a rate that covers our costs, including research, development, intellectual property, manufacture, sale and distribution expenses. Interim reimbursement levels for new products, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the product and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost products and may be incorporated into existing payments for other services. Net prices for products may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors, by any future laws limiting drug prices and by any future relaxation of laws that presently restrict imports of product products from countries where they may be sold at lower prices than in the United States.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In the United States, there is no uniform policy among third-party payors for coverage and reimbursement. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting reimbursement policies, but also

have their own methods and approval process apart from Medicare coverage and reimbursement determinations. Therefore, one third-party payor's determination to provide coverage for a product does not assure that other payors will also provide coverage for the product.

Coverage and reimbursement by a third-party payor may depend upon a number of factors, including 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.

We cannot be sure that reimbursement will be available for any product that we commercialize and, if coverage and reimbursement are available, what the level of reimbursement will be. Our inability to promptly obtain coverage and adequate reimbursement rates from both government-funded and private payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

Reimbursement may impact the demand for, and the price of, any product for which we obtain marketing approval. Even if we obtain coverage for a given product by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. Patients who are prescribed medications for the treatment of their conditions, and their prescribing physicians, generally rely on third-party payors to reimburse all or part of the costs

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associated with those medications. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover all or a significant portion of the cost of our products. Therefore, coverage and adequate reimbursement are critical to a new product's acceptance. Coverage decisions may depend upon clinical and economic standards that disfavor new products when more established or lower cost therapeutic alternatives are already available or subsequently become available.

For products administered under the supervision of a physician, obtaining coverage and adequate reimbursement may be particularly difficult because of the higher prices often associated with such drugs. Additionally, separate reimbursement for the product itself may or may not be available. Instead, the hospital or administering physician may be reimbursed only for providing the treatment or procedure in which our product is used. Further, from time to time, the CMS, the federal agency responsible for administering the Medicare program, revises the reimbursement amounts paid to health care providers, including the Medicare Physician Fee Schedule and Hospital Outpatient Prospective Payment System, which may result in reduced Medicare payments.

We expect to experience pricing pressures in connection with the sale of any of our product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations, and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription medicines, medical devices and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the successful commercialization of new products. Further, the adoption and implementation of any future governmental cost containment or other health reform initiative may result in additional downward pressure on the price that we may receive for any approved product.

Outside of the United States, many countries require approval of the sale price of a product before it can be marketed, and the pricing review period only begins after marketing or product licensing approval is granted. To obtain reimbursement or pricing approval in some of these countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product candidate in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenue, if any, we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if such product candidates obtain marketing approval.

Reimbursement and healthcare payment systems vary significantly by country outside the US, United States, and many countries have instituted price ceilings on specific products and therapies. In the EU and the UK, United Kingdom, similar political, economic and regulatory developments may affect our ability to profitably commercialize our product candidates, if approved. In addition to continuing pressure on prices and cost containment measures, legislative developments at the EU, UK United Kingdom or at a an EU Member State level may result in significant additional requirements or obstacles that may increase our operating costs. The delivery of healthcare in the EU, and the UK, including the establishment and operation of health services and the pricing and reimbursement of medicines, is almost exclusively a matter for national, rather than EU, law and policy. National governments and health service providers have different priorities and approaches to the delivery of health care and the pricing and reimbursement of products in that context. In general, however, the healthcare budgetary constraints in most EU Member States and the UK United Kingdom have resulted in restrictions on the pricing and reimbursement of medicines by relevant health service providers. Coupled with ever-increasing EU and national regulatory burdens on those wishing to develop and market products in these

countries, this these restrictions on pricing and reimbursement could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to commercialize our product candidates, if approved.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action in the US, United States, the EU, UK United Kingdom or any other jurisdiction. If we, or any third parties we may engage, are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or such third parties are not able to maintain regulatory compliance, our product candidates may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability.

If the regulatory authorities in such jurisdictions set prices or make reimbursement criteria that are not commercially attractive for us or our collaborators, our revenues and the potential profitability of our products in those countries would be negatively affected.

If the market opportunities for any of our product candidates are smaller than we believe they are, our revenue may be adversely affected, and our business may suffer.

We are focused on the development of treatments for cancer. Our projections of addressable patient populations that have the potential to benefit from treatment with our product candidates are based on estimates, including estimated incidence rates of specific forms of cancer. If any of our estimates are inaccurate, the market opportunities for any of our product candidates could be significantly diminished and have an adverse material impact on our business.

If any of our product candidates are approved for marketing and commercialization and we are unable to establish sales and marketing capabilities or enter into agreements with third parties to sell and market our product candidates, we will be unable to successfully commercialize our product candidates if and when they are approved.

We have no sales, marketing or distribution capabilities or experience. To achieve commercial success for any approved product for which we retain sales and marketing responsibilities, we must either develop a sales and marketing organization, which would be expensive and time consuming, or outsource these functions to other third parties. In the future, we may choose to build a focused sales and marketing infrastructure to sell, or participate in sales activities with our collaborators for, some of our product candidates if and when they are approved.

There are risks involved with both establishing our own sales and marketing 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, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel. Factors that may inhibit our efforts to commercialize future products on our own include:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to compliantly obtain access to physicians or educate adequate numbers of physicians on the benefits of prescribing any future product
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive p portfolios; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

If we enter into arrangements with third parties to perform sales, marketing and distribution services, our product revenue or the profitability of the product revenue to us are likely to be lower than if we were to market and sell any products that we develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell and market our product candidates or may be unable to do so on terms that are favorable to us. In entering into third-party marketing or distribution arrangements, any revenue we receive will depend upon the efforts of the third parties and we cannot assure you that such third parties will establish adequate sales and distribution capabilities or devote the necessary resources and attention to sell and market any future products effectively. If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates.

Regulatory If granted, regulatory approval by the FDA, European Commission (based on recommendations from the EMA) or comparable foreign regulatory authorities is limited to those specific indications and conditions for which approval has been granted, and we may be subject to substantial fines, criminal penalties, injunctions, or other enforcement actions if we are determined to be promoting the use of our products for unapproved or "off-label" off-label uses, or in a manner inconsistent with the approved labeling, resulting in damage to our reputation and business.

We must comply with requirements concerning advertising and promotion for any product candidates for which we obtain marketing approval. Promotional communications with respect to therapeutics are subject to a variety of legal and regulatory restrictions and continuing review by the FDA or comparable foreign regulatory and governmental authorities, Department of Justice, HHS Office of Inspector General, state attorneys general, members of Congress, and the public. When the FDA or comparable foreign regulatory authorities issue regulatory approval for a product candidate, the regulatory approval is limited to those specific uses and indications for which a the product is has been approved. If we are not able to obtain FDA or comparable foreign regulatory authority approval for desired uses or indications for our current product candidates and any future product candidates, we may not market or promote them for those indications and uses, referred to as off-label uses, and our business, financial condition, results of operations, stock price and prospects will be materially harmed. We also must sufficiently substantiate any claims that we make for our products, including claims comparing our products to other companies' products, and must abide by the FDA or a comparable foreign regulatory or governmental authority's strict requirements regarding the content of promotion and advertising.

While physicians may choose to prescribe products for uses that are not described in the product's labeling and for uses that differ from those tested in clinical trials and approved by the regulatory authorities, we and any third parties engaged on our behalf are prohibited from marketing and promoting the products for indications and uses that are not specifically approved by the FDA or comparable foreign regulatory authorities. Regulatory authorities in the United States generally do not restrict or regulate the behavior of physicians in their choice of treatment within the practice of medicine. Regulatory authorities do, however, restrict communications by biopharmaceutical companies concerning off-label use.uses.

If we are found to have impermissibly promoted any of our current product candidates and any future product candidates, we may become subject to significant liability and government fines. The FDA and other agencies actively enforce the laws and regulations regarding product promotion, particularly those prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted a product may be subject to significant sanctions. The federal government has levied large civil and criminal fines against companies for alleged improper promotion 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.

In the United States, engaging in the impermissible promotion of our products, following approval, for off-label uses can also subject us to false claims and other litigation under federal and state statutes. These include fraud and abuse and consumer protection laws, which can lead to civil and criminal penalties and fines, and agreements with governmental authorities that materially restrict the manner in which we promote or distribute therapeutic products and conduct our business. These restrictions could include corporate integrity agreements, suspension or exclusion from participation in federal and state healthcare programs, and suspension and debarment from government contracts and refusal of orders under existing government contracts. These FCA lawsuits against manufacturers of drugs and biologics have increased significantly in volume and breadth, leading to several substantial civil and criminal settlements pertaining to certain sales practices and promoting off-label uses. In addition, FCA lawsuits may expose manufacturers to follow-on claims by private payors based on fraudulent marketing practices. This growth in litigation has increased the risk that a biopharmaceutical company will have to defend a false claim action, pay settlement fines or restitution, as well as criminal and civil penalties, agree to comply with burdensome reporting and compliance obligations, and be excluded from Medicare, Medicaid, or other federal and state healthcare programs. If we do not lawfully promote our approved products, if any, we may become subject to such litigation and, if we do not successfully defend against such actions, those actions may have a material adverse effect on our business, financial condition, results of operations, stock price and prospects.

In the United States, the promotion of biopharmaceutical products are subject to additional FDA requirements and restrictions on promotional statements. If after one or more of our current or future product candidates obtains marketing approval the FDA determines that our promotional activities violate its regulations and policies pertaining to product promotion, it could request that we modify our promotional materials or subject us to regulatory or other enforcement actions, including issuance of warning letters or untitled letters, suspension or withdrawal of an approved product from the market, requests for recalls, payment of civil fines, disgorgement of money, imposition of operating restrictions, injunctions or criminal prosecution, and other enforcement actions. Similarly, industry codes in foreign jurisdictions may prohibit companies from engaging in certain promotional activities and regulatory agencies in various countries may enforce violations of such codes with civil penalties. If we become subject to regulatory and enforcement actions our business, financial condition, results of operations, stock price and prospects will be materially harmed.

Furthermore, the use of our products for indications other than those approved by the FDA or comparable foreign regulatory authorities may not effectively treat such conditions. Any such off-label use of our product candidates could harm our reputation in the marketplace among physicians and patients. There may also be increased risk of injury to patients if physicians attempt to use our products for these uses for which they are not approved, which could lead to product liability suits that that might require significant financial and management resources and that could harm our reputation.

Even if we obtain FDA or European Commission (based on recommendations from the EMA) approval of any of our product candidates in the United States or EU, we may never obtain approval for or commercialize any of them in any other jurisdiction, which would limit our ability to realize their full market potentialpotential.

In order to market any products in any particular jurisdiction, we must establish and comply with numerous and varying regulatory requirements on a country-by-country basis regarding safety and efficacy.

Approval by the FDA in the United States or the European Commission (based on recommendations from the EMA) in the EU does not ensure approval by regulatory authorities in other countries or jurisdictions. However, the failure to obtain approval in one jurisdiction may negatively impact our ability to obtain approval elsewhere. In addition, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not guarantee regulatory approval in any other country.

Approval processes vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approval could result in difficulties and increased costs for us and require additional preclinical studies or clinical trials which could be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. We do not have any product candidates approved for sale in any jurisdiction, including in international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approvals in international markets are delayed, our target market will be reduced and our ability to realize the full market potential of any product we develop will be unrealized.

Risks Related to Reliance on Third Parties

Some of our product candidates may be studied in clinical trials sponsored by organizations or agencies other than us, or in investigator-initiated clinical trials, which means we will have minimal or no control over the conduct of such trials.

We have supplied and may continue to supply and otherwise support third party research, including investigator-initiated clinical trials. Investigator-initiated clinical trials pose similar risks as those set forth elsewhere in this “Risk Factor” section relating to our internally-sponsored clinical trials, but because we may not be the sponsors of these trials, we have less control over the protocols, administration or conduct of these trials, including follow-up with patients and ongoing collection of data after treatment. The conduct or findings of these trials may have a negative impact on our development programs notwithstanding that we have little involvement or control over these trials. As a result, we are subject to additional risks associated with the way investigator-initiated trials are conducted. In particular, we may be named in lawsuits that would lead to increased costs associated with legal defense. Additional risks include difficulties or delays in communicating with investigators or administrators, procedural delays and other timing issues and difficulties or differences in interpreting data. Third-party investigators may design clinical trials 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 that we may design on our own. Negative results in investigator-initiated clinical trials could have a material adverse effect on our efforts to obtain regulatory approval for our product candidates and the public perception of our product candidates. As a result, our lack of control over the conduct and timing of and communications with the FDA and other regulatory authorities regarding investigator-sponsored trials may expose us to additional risks and uncertainties, many of which are outside our control, and the occurrence of which could adversely affect the commercial prospects for our product candidates.

We rely on third parties to conduct, supervise, and monitor our clinical trials and perform some of our research and preclinical studies. If these third parties do not satisfactorily carry out their contractual duties or fail to meet expected deadlines, our development programs may be delayed or subject to increased costs each of which may have an adverse effect on our business and prospects.

We do not have the ability to conduct all aspects of our preclinical testing or clinical trials ourselves. As a result, we are and expect to remain dependent on third parties to conduct our current and future preclinical studies and clinical trials. CROs that manage our preclinical studies and clinical trials as well as clinical investigators, including in investigator-initiated clinical trials, and consultants play a significant role in the conduct of our preclinical studies and clinical trials and the subsequent collection and analysis of data. The timing of the initiation and completion of these studies and trials will therefore be partially controlled by such third parties and may result in delays to our development programs. Nevertheless, we are responsible for ensuring that each of our preclinical studies and clinical trials is conducted in accordance with the applicable protocol, legal requirements, and

scientific standards, and our reliance on the CROs and other third parties does not relieve us of our regulatory responsibilities. We and our CROs are required to comply with Good Laboratory Practice (GLP) and GCP requirements, which are regulations and guidelines enforced by the FDA, the EMA, and comparable foreign regulatory authorities for all of our product candidates in clinical development. Regulatory authorities enforce these GLP and GCP requirements through periodic inspections of preclinical study sites, trial sponsors, clinical trial investigators and clinical trial sites. If we or any of our CROs or clinical trial sites, including clinical trial sites in investigator-initiated clinical trials, fail to comply with applicable GLP or GCP requirements, the data generated in our preclinical studies and clinical trials may be deemed unreliable, and the FDA, EMA, or comparable foreign regulatory authorities may require us to perform additional preclinical or clinical trials before

approving our marketing applications. Further, requirements regarding clinical trial data may evolve. In June 2023, the FDA published a draft guidance, "E6(R3) Good Clinical Practice (GCP)," which seeks to unify standards for clinical trial data for ICH member countries and regions. Changes to data requirements may cause the FDA or other foreign regulatory authorities to disagree with data from preclinical studies or clinical trials, and may require further studies. In addition, our clinical trials must be conducted with product produced under cGMP regulations. Our failure to comply with these regulations may require us to stop and/or repeat clinical trials, which would delay the marketing approval process.

There is no guarantee that any such CROs, clinical trial investigators or other third parties on which we rely will devote adequate time and resources to our development activities or perform as contractually required. These risks are heightened as a result of the efforts of government agencies and the CROs themselves to limit the spread of COVID-19, including quarantines and shelter-in-place orders. If any of these third parties fail fails to meet expected deadlines, fails to adhere to our clinical protocols or meet regulatory requirements, otherwise performs in a substandard manner, or terminates its engagement with us, the timelines for our development programs may be extended or delayed or our development activities may be suspended or terminated. If any of our clinical trial sites terminates for any reason, we may experience the loss of follow-up information on subjects enrolled in such clinical trials unless we are able to transfer those subjects to another qualified clinical trial site, which may be difficult or impossible. In addition, clinical trial investigators for our clinical trials or investigator-initiated clinical trials may serve as scientific advisors or consultants to us from time to time and may receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, or the FDA or any comparable foreign regulatory authority concludes that the financial relationship may have affected the interpretation of the trial, the integrity of the data generated at the applicable clinical trial site may be questioned and the utility of the clinical trial itself may be jeopardized, which could result in the delay or rejection of any marketing application we submit by the FDA or any comparable foreign regulatory authority. Any such delay or rejection could prevent us from commercializing our product candidates.

Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not may be able unable to obtain, or may be delayed in obtaining, marketing approvals for our product candidates and will not may be able unable to, or may be delayed in our efforts to, successfully commercialize our products.

We rely on third parties to manufacture our product candidates, and we expect to continue to rely on third parties for the clinical as well as any future commercial supply of our product candidates and other future product candidates. The development of our current and future product candidates, and the commercialization of any approved products, could be stopped, delayed or made less profitable if any such third party fails to provide us with sufficient clinical or commercial quantities of such product candidates or products, fails to do so at acceptable quality levels or prices or fails to achieve or maintain satisfactory regulatory compliance.

We do not currently have, and we do not plan to build, the infrastructure or capability internally to manufacture current product candidates or any future product candidates for use in the conduct of our clinical trials or, if approved, for commercial supply. We rely on, and expect to continue to rely on, CMOs. Reliance on third-party providers may expose us to more risk than if we were to manufacture our product candidates ourselves. We do not control the manufacturing processes of the CMOs we contract with and are dependent on those third parties for the production of our product candidates in accordance with relevant applicable regulations such as cGMP, which includes, among other things, quality control, quality assurance and the maintenance of records and documentation.

In complying with the manufacturing regulations of the FDA and other comparable foreign regulatory authorities, we and our third-party suppliers must spend significant time, money and effort in the areas of design and development, testing, production, record-keeping and quality control to assure that the products meet applicable specifications and other regulatory requirements. The failure to comply with these requirements could result in an enforcement action against us, including the seizure of products and shutting down of production. We and any of these third-party suppliers may also be subject to inspections by the FDA, EU Member States coordinated (coordinated by the EMA, EMA), or comparable foreign regulatory authorities. If any of our third-party suppliers fails to comply with cGMP or other applicable manufacturing regulations, our ability to develop and commercialize our product candidates could suffer significant interruptions.

Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or drugs, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products.

Any disruption, such as a fire, natural hazards or vandalism at our CMOs, or any impacts on our CMOs due to the COVID-19, pandemic, could significantly interrupt our manufacturing capability. We currently do not have alternative production plans in place or disaster-recovery facilities available. In case of a disruption, we will have to establish alternative

manufacturing sources. This would require substantial capital on our part, which we may not be able to obtain on commercially acceptable terms or at all. Additionally, we would likely experience months of manufacturing delays as we build facilities or locate alternative suppliers and seek and obtain necessary regulatory approvals. If this occurs, we will may be unable to satisfy manufacturing needs on a timely basis, if at all. If changes to CMOs occur, then there also may be changes to manufacturing processes inherent in the setup of new operations for our product candidates and any products that may obtain approval in the future. Any such changes could require the conduct of bridging studies before we can use any materials produced at new facilities or under new processes in clinical trials or, for any products reaching approval, in our commercial supply. Further, business interruption insurance may not adequately compensate us for any losses that may occur and, in that case, we would have to bear the additional cost of any disruption. For these reasons, a significant disruptive event of any CMOs could have drastic consequences, including placing our financial stability at risk.

Our product candidates and any drugs that we may develop may compete with other product candidates and drugs for access to manufacturing facilities. There are no assurances we would be able to enter into similar commercial arrangements with other manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us. Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval.

If we were to experience an unexpected loss of supply of or if any supplier were unable to meet our clinical or commercial demand for any of our product candidates, we could experience delays in our planned clinical studies or commercialization. For example, the COVID-19 pandemic future public health emergencies may impact our ability to procure sufficient supplies for the development of our current and future product candidates, and the extent of such impacts will depend on the severity and duration of the spread of the virus and the actions undertaken to contain COVID-19 such public health crisis or treat its effects. We could be unable to find alternative suppliers of acceptable quality and experience that can produce and supply appropriate volumes at an acceptable cost or on favorable terms. Moreover, our suppliers are often subject to strict manufacturing requirements and rigorous testing requirements, which could limit or delay production. The long transition periods necessary to switch manufacturers and suppliers, if necessary, would could significantly delay our clinical trials and, for any product candidates that reach approval, the commercialization of our products, which would materially adversely affect our business, financial condition and results of operation.

We depend on third-party suppliers for materials that are necessary for the conduct of preclinical studies and manufacture of our product candidates for clinical trials, and the loss of these third-party suppliers or their inability to supply us with sufficient quantities of adequate materials, or to do so at acceptable quality levels and on a timely basis, could harm our business.

Manufacturing our product candidates requires many reagents, which are substances used in our manufacturing processes to bring about chemical or biological reactions, and other specialty materials and equipment, some of which are manufactured or supplied by small companies with limited resources and experience to support commercial biologics production. We currently depend on a limited number of vendors for certain materials and equipment used in the manufacture of our product candidates. For example, we currently use facilities and equipment at external CMOs, as well as supply sources internal to the collaboration for vector supply. Our use of CMOs increases the risk of delays in production or insufficient supplies as we transfer our manufacturing technology to these CMOs and as they gain experience with our supply requirements. Some of these suppliers may not have the capacity to support 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.

For some of these reagents, equipment, and materials, we rely and may in the future rely on sole source vendors or a limited number of vendors. The supply of the reagents and other specialty materials and equipment that are necessary to produce our product candidates could be reduced or interrupted at any time. In such case, identifying and engaging an alternative supplier or manufacturer could result in delay, and we may not be able to find other acceptable suppliers or manufacturers on acceptable terms, or at all. Switching suppliers or manufacturers may involve substantial costs and is likely to result in a delay in our desired clinical and commercial timelines. If we change suppliers or manufacturers for commercial production, applicable regulatory agencies may require us to conduct additional studies or trials. If key suppliers or manufacturers are lost, or if the supply of the materials is diminished or discontinued, we may not be able to develop, manufacture and market our product candidates in a timely and competitive manner, or at all. An inability to continue to source product from any of these suppliers, which could be due to a number of issues, including regulatory actions or requirements affecting the supplier, adverse financial or other strategic developments experienced by a supplier, labor disputes or shortages, unexpected demands or quality issues, could adversely affect our ability to

satisfy demand for our 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.

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As we continue 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. These factors could cause the delay of studies or trials, regulatory submissions, required approvals or commercialization of product candidates that we develop, cause us to incur higher costs and prevent us from commercializing our product candidates successfully.

Our reliance on third parties requires us to share certain of our trade secrets, which increases the possibility that a competitor will discover them or that our such trade secrets will be misappropriated or disclosed.

Because we rely on third parties to research and develop and to manufacture our product candidates, we must share trade secrets with them. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements or other similar agreements with our advisors, employees, third-party contractors and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's independent discovery of our trade secrets or other unauthorized use or disclosure would could impair our competitive position and may have a material adverse effect on our business.

In addition, these agreements typically restrict the ability of our advisors, employees, third-party contractors and consultants to publish data potentially relating to our trade secrets, although our agreements may contain certain limited publication rights. For example, any academic institution that we may collaborate with will likely expect to be granted rights to publish data arising out of such collaboration and any joint research and development programs may require us to share trade secrets under the terms of our research and development or similar agreements. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of our agreements with third parties, independent development or publication of information by any of our third-party collaborators. A competitor's discovery of our trade secrets would could impair our competitive position and have an adverse impact on our business.

We may form or seek partnerships, collaborations or strategic alliances or enter into additional licensing arrangements in the future, and we may not realize the benefits of such partnerships, collaborations, alliances or licensing arrangements.

We may form or seek partnerships or strategic alliances, create joint ventures or collaborations, or enter into licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our product candidates and any future product candidates that we may develop. For example, we have entered into collaborative agreements with Merck pursuant to which they provide the pembrolizumab used in certain of our trials. Any of these relationships may require us to incur non-recurring and other charges, increase our near and long-term expenditures, require us to share the data with such collaborators, or restrict our ability to utilize certain data arising out of these collaboration arrangements, issue securities that dilute our existing stockholders or take actions that disrupt our management and business.

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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 and obtain marketing approval.

Further, collaborations involving our product candidates are subject to numerous risks, which may include the following:

- 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 product candidates based on clinical trial results,

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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 t 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;
- collaborators 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 or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes, including contract disputes, may arise between us and a collaborator that cause the delay or termination of the research, development or commercialization 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 p candidates; and
- collaborators may own or co-own intellectual property covering our products that results from our collaborating with them, and in such cases, we would not ha exclusive right to commercialize such intellectual property.

As a result, if we enter into additional 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. We also cannot be certain that, following a strategic transaction or license, we will achieve the revenue 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.

Risks Related to Our Industry and Business Operations

The outbreak of COVID-19, or similar public health crises, emergencies, could have a material adverse impact on our business, financial condition and results of operations, including the execution of our planned clinical trials.

In December 2019, a novel strain of coronavirus, SARS-CoV-2, was identified. This virus has since spread globally, including within the United States and, while the COVID-19 public health emergency expired on May 11, 2023 and cases and hospitalization are currently on the decline in the United States, there can be no assurances they will not continue at the current rate or increase in the future especially in light of the number of variants that are emerging across the world. Governments in the United States and elsewhere have historically taken and are continuing to may in the future take severe measures to slow the spread of COVID-19, including by requiring that certain businesses close or conduct only the minimum necessary operations. The pandemic and government measures taken in response have also had a significant impact, both direct and indirect, on businesses and commerce, as worker shortages have occurred, supply chains have been were disrupted, facilities and were closed, production have been was suspended, and demand for certain goods and services, such as medical services and supplies, has spiked, while demand for other goods and services, such as travel, has fallen. fell. The extent to which COVID-19 will continue to and similar public health emergencies may impact our business and operating results will depend on future developments that are highly uncertain and cannot be accurately predicted, including new information that may emerge concerning COVID-19 and similar public health emergencies and government measures taken in response.

Site activation, participant recruitment and enrollment, participant dosing, distribution of clinical trial materials, study monitoring and data analysis for our planned clinical trials may be delayed due to changes in hospital or university policies, federal, state or local regulations, prioritization of hospital resources toward pandemic efforts, or other reasons related to the pandemic. COVID-19 or similar public health emergencies. Additionally, some participants and clinical investigators may not be able to comply with clinical trial protocols. protocols in light of future restrictions imposed by the U.S. and other foreign governments. For example, quarantines or other travel limitations (whether voluntary or required) may impede participant movement, affect sponsor access to study sites, or interrupt healthcare services, and we may be unable to conduct its planned clinical trials. If the global effort to control the spread of public health emergencies such as COVID-19 and treat COVID-19 patients continues for an extended period of time, we risk a delay in activating sites and enrolling subjects as previously projected. For example, during COVID-19, we have experienced longer than

expected lead times in clinical trial site activation and patient enrollment in our clinical trials. Any delays to our planned clinical trials for IO102-IO103 and any future clinical trials and increased cost associated with the conducting of our clinical trials could impact the use and sufficiency of our existing cash reserves, and we may be required to raise additional

capital earlier than it had previously planned. We may be unable to raise additional capital if and when needed, which may result in further delays or suspension of our development plans.

Further, infections and deaths related to COVID-19 are disrupting and similar public health emergencies have disrupted, and may disrupt in the future, certain healthcare and healthcare regulatory systems globally. Such disruptions could divert healthcare resources away from, or materially delay review by, the FDA and comparable foreign regulatory agencies. It is unknown how long these disruptions could continue, were they to occur. Any elongation or de-prioritization of our clinical trials or delay in regulatory review resulting from such disruptions could materially adversely affect the development and study of its product candidates.

We currently utilize third parties to, among other things, manufacture raw materials and our product candidates, components, parts, and consumables, and to perform quality testing. If either we or any third-party in the supply chain for materials used in the production of its product candidates are adversely impacted by restrictions resulting from the COVID-19 pandemic, or similar public health emergencies, our supply chain may be disrupted, limiting our ability to manufacture product candidates for its clinical trials.

In response to the COVID-19, pandemic, we complied with applicable regulation and limited required on-site staff to essential workers, with the balance of its employees continuing their work primarily outside of our offices. Due to shelter-in-place orders or other mandated local travel restrictions, third parties conducting clinical or manufacturing activities may were not be able to access laboratory or manufacturing space, and, should future public health emergencies necessitate similar action, our core activities may be significantly limited or curtailed, possibly for an extended period of time.

While the potential economic impact brought by and the duration of the pandemic public health emergencies may be difficult to assess or predict, it has already COVID-19 caused, and is likely to result may in further, the future cause, significant disruption of global financial markets and the trading prices of biopharmaceutical companies have been was highly volatile as a result of the COVID-19 pandemic, which may reduce our ability to access capital either at all or on favorable terms. In addition, a recession, depression or other sustained adverse market event resulting from the global effort to control COVID-19 infections future public health emergencies could materially and adversely affect our business.

The ultimate impact of the current pandemic, COVID-19, or any other health epidemic, is highly uncertain and subject to change. We do not yet know the full extent of potential Potential delays or impacts on our business, our planned clinical trials, healthcare systems or the global economy as a whole. However, these effects whole could have a material adverse impact on our business, financial condition and results of operations.

Disruptions at the FDA, EMA, SEC and other government agencies and regulatory authorities caused by funding shortages or global health concerns could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal governmental functions on which the operation of our business may rely, which could negatively impact our business.

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

Disruptions at the FDA and other agencies such as the EMA following its post-Brexit relocation and resulting staff changes as well as necessary COVID-19 prioritizations may also slow the time necessary for new products to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, in recent years, including in 2018 and 2019, the U.S. government shut down several times and certain regulatory agencies, such as the FDA and the SEC, had to furlough critical employees and stop critical activities. If a prolonged government shutdown occurs in the future, it could significantly impact the ability of the FDA to review and process our regulatory submissions, which could have a material adverse effect on our business. Further, upon completion of our IPO and in our operations as a public company, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

Separately, in response to the COVID-19 pandemic, Since March 2020, when foreign and domestic inspections of facilities were largely placed on March 10, 2020 hold, the FDA announced its intention has been working to postpone most resume routine surveillance, bioresearch monitoring, and pre-approval inspections of foreign manufacturing facilities, and on March 18, 2020, a prioritized basis. Since April 2021, the FDA temporarily postponed routine

surveillance has conducted limited inspections of domestic manufacturing facilities. On July 10, 2020, the FDA announced its intention to resume certain on-site inspections of domestic manufacturing facilities subject to a risk-based prioritization system. On April 14, 2021, the FDA issued a guidance document in which the FDA described its plans to conduct voluntary and employed remote interactive evaluations, of certain drug manufacturing facilities using risk management methods, to meet user fee commitments and clinical research sites. According goal dates. Travel restrictions and other uncertainties may continue to the guidance, impact oversight operations both domestic and abroad. Should the

FDA determine that an inspection is necessary for approval and an inspection cannot be completed during the review cycle due to restrictions on travel, and the FDA does not determine a remote interactive evaluation to be adequate, the agency has stated that it generally intends to request such remote interactive evaluations in situations where issue, depending on the circumstances, a complete response letter or defer action on the application until an in-person inspection would not can be prioritized, deemed mission-critical, or where direct inspection is otherwise limited by travel restrictions, but where the FDA determines that remote evaluation would still be appropriate. In May 2021, the FDA outlined a detailed plan to move toward a more consistent state of inspectional operations, and in July 2021, the FDA resumed standard inspectional operations of domestic facilities and was continuing to maintain this level of operation as of September 2021. In November 2021, the FDA provided an update to the May 2021 "Resiliency Roadmap for FDA Inspectional Oversight," noting completion of "mission-critical" work over the previous year. In the update, the FDA noted that it "is continuing to complete mission-critical work, prioritize other higher-tiered inspectional needs (e.g., for-cause inspections), and carry out surveillance inspections using risk-based approaches for evaluating public health impact." Further, ongoing surges in COVID-19 case numbers, with the emergence of new variants and sub-variants, have contributed to interruptions in FDA's surveillance capabilities. In light of high positivity rates and hospitalizations associated with COVID-19, the FDA made temporary changes in late 2021, including temporarily postponing certain inspection activities from December 29, 2021 to January 19, 2022. completed. On February 2, 2022, the FDA announced that it would resume domestic surveillance inspections across all product areas on February 7, 2022. We cannot predict whether

On May 11, 2023, the COVID-19 public health emergency declared under the Public Health Service (PHS) Act expired. It is unclear how the FDA's policies and when guidance will impact any inspections of our facilities, including our clinical trial sites. During the FDA will decide to pause or resume inspections COVID-19 public health emergency, a number of companies announced receipt of complete response letters due to the COVID-19 pandemic.

More recently, the FDA has continued FDA's inability to monitor and implement changes to its inspectional activities to ensure the safety of its employees and those of the firms it regulates as it adapts to the evolving COVID-19 pandemic. complete required inspections for their applications. Regulatory authorities outside of the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. and may experience delays in their regulatory activities.

If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their impact regular inspections, reviews, or other regulatory activities of the FDA or other regulatory authorities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

The United Kingdom's withdrawal from the EU may cause additional administrative burdens and strain on regulatory authorities in the EU, this may delay our ability to obtain regulatory approvals of our product candidates in the EU and may require us to incur additional expenses in order to develop, manufacture and commercialize our product candidates in the EU.

The UK formally exited the EU, commonly referred to as Brexit, on January 31, 2020. Under the terms of its departure, the UK entered a transition period (the Transition Period), during which it continued to follow all EU rules. The Transition Period ended on December 31, 2020. On December 30, 2020, the UK and EU signed the Trade and Cooperation Agreement (TCA), which includes an agreement on free trade between the two parties. The TCA does not contain wholesale mutual recognition of regulatory regimes for pharmaceuticals as was hoped. There is mutual recognition of cGMP inspections of manufacturing facilities but it does not include reciprocal arrangements for the recognition of batch testing certification, in order to avoid unnecessary re-testing on importation of products.

There is considerable uncertainty resulting from a lack of precedent and the complexity of the UK and the EU's intertwined legal regimes as to how Brexit will impact the life sciences industry in Europe, including our company, including with respect to ongoing or future clinical trials. The impact will largely depend on the model and means by which the UK's relationship with the EU is governed post-Brexit and the extent to which the UK chooses to diverge from the EU regulatory framework.

The regulatory framework for medicines that existed before the end of the transition period has effectively been preserved in UK domestic legislation as 'retained EU law' which has prevented substantial divergence to the regulation of medicines. However, some changes to the UK legislation have been immediately necessary, including the implementation of the Northern Ireland Protocol (NIP), pursuant to which, the EU pharmaceutical legal framework acquis continues to apply in Northern Ireland (subject to periodic consent of the Northern Ireland Legislative Assembly), and only products compliant with EU law can be placed in the Northern Ireland market - adding an extra layer of regulatory complexity. As companies now need to comply with a separate UK regulatory legal framework in order to commercialize medicinal products in Great Britain (namely, England, Wales and Scotland, as EU law continues to apply in Northern Ireland). The UK government is currently trying to renegotiate fundamental aspects of the Northern Ireland Protocol so this is an unpredictable area for companies in the near future. The Trade and Cooperation Agreement signed between the UK and the EU allows for future deviation from the current regulatory framework and it is not known if and/or when any deviations may occur, which may have an impact on development, manufacture, marketing authorization, commercial sales and distribution of pharmaceutical products.

Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of Brexit or otherwise, would prevent us from or delay us commercializing our product candidates in the UK and/or the European Economic Area (EEA) and restrict our ability to generate revenue and achieve and sustain profitability. In the short term, there is a risk of disrupted import and export processes due to a lack of administrative processing capacity by the respective United Kingdom and EU customs agencies that may delay time-sensitive shipments and may negatively impact our product supply chain.

We may be exposed to significant foreign exchange risk.

We have operations in Denmark and we incur portions of our expenses, and may in the future derive revenues, in a variety of currencies. As a result, we are exposed to foreign currency exchange risk as our results of operations and cash flows are subject to fluctuations in foreign currency exchange rates. Fluctuations in currency exchange rates

have had, and will continue to have, an impact on our results as expressed in U.S. dollars. We currently do not engage in hedging transactions to protect against uncertainty in future exchange rates between particular foreign currencies and the U.S. dollar. We cannot predict the impact of foreign currency fluctuations, and foreign currency fluctuations in the future may adversely affect our financial condition, results of operations and cash flows.

Our employees, principal investigators, consultants and commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading.

We are exposed to the risk of fraud or other misconduct by our employees, principal investigators, consultants and commercial partners. Misconduct by these parties could include intentional failures to comply with the regulations of the FDA and other comparable foreign regulatory authorities, provide accurate information to the FDA and other comparable foreign regulatory authorities, comply with healthcare fraud and abuse laws and regulations in the United States, EU, UK, United Kingdom and in other jurisdictions, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Such misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, contractual damages, reputational harm, diminished profits and future earnings, additional reporting obligations and oversight if subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations.

We face potential product liability, and, if successful claims are brought against us, we may incur substantial liability and costs. if If the use of our product candidates harms patients or is perceived to harm patients even when such harm is unrelated to our product candidates, our regulatory approvals could be revoked or otherwise negatively impacted and we could be subject to costly and damaging product liability claims.

The use of our product candidates in clinical trials and the sale of any products for which we obtain marketing approval exposes us to the risk of product liability claims. Product liability claims might be brought against us by consumers, healthcare providers, pharmaceutical companies or others selling or otherwise coming into contact with our products. There is a risk that our product candidates may induce adverse events. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- impairment of our business reputation;
- withdrawal of clinical trial participants;
- costs due to related litigation;
- distraction of management's attention from our primary business;
- substantial monetary awards to patients or other claimants;
- the inability to commercialize our product candidates; and
- decreased demand for our product candidates, if approved for commercial sale.

We believe our product liability insurance coverage is sufficient in light of our current clinical programs; however, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. If and when we obtain marketing approval for product candidates, we intend to expand our insurance coverage to include the sale of commercial products; however, we may be unable to obtain product liability insurance on commercially reasonable terms or in adequate amounts. On occasion, large judgments have been awarded in class action lawsuits based on drugs or medical treatments that had unanticipated adverse effects. A successful product liability claims or series of claims brought against us could cause our stock price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business.

Patients with cancer and other diseases targeted by our product candidates are often already in severe and advanced stages of disease and have both known and unknown significant pre-existing and potentially life-threatening health risks. During the course of treatment, patients may suffer adverse events, including death, for reasons that may be related to, or perceived to be related to, our product candidates. Such events could subject us to costly litigation, require us to pay substantial amounts of money to injured patients, delay, negatively impact or end our opportunity to receive or maintain regulatory approval to market our products, or require us to suspend or abandon our commercialization efforts. Even in a circumstance in which we do not believe that an adverse event is related to our products, the investigation into the circumstance may be time-consuming or inconclusive. These investigations may divide the attention of our management team, interrupt our sales efforts, delay our regulatory approval process in other countries, or impact and limit the type of regulatory approvals our product candidates receive or maintain. As a result of these factors, a product liability claim, even if successfully defended, could have a material adverse effect on our business, financial condition or results of operations.

Our future success depends on our ability to retain key members of senior management and to attract, retain and motivate qualified personnel.

Our ability to compete in the highly competitive biopharmaceutical industry depends upon our ability to attract and retain highly qualified management, research and development, clinical, financial and business development personnel. We are highly dependent on our management, scientific and medical personnel, including Mai Britt Zocca, Ph.D., our Chief Executive Officer, Amy Sullivan, M.B.A., our Chief Financial Officer Eva Ehrnrooth, and Qasim Ahmad, M.D., Ph.D., our Chief Medical Officer, and Muhammad Al-Hajj, Ph.D., our Chief Scientific Officer. Our senior management may terminate their employment with us at any time. We do not maintain “key person” insurance for any of our employees.

Recruiting and retaining qualified scientific and clinical personnel and, if we progress the development of any of our product candidates, commercialization, manufacturing and sales and marketing personnel, will be critical to our success. The loss of the services of members of our senior management or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing members of our senior management and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize our product candidates. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level and senior managers, as well as junior, mid-level and senior scientific and medical personnel. Competition to hire from this limited candidate pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high-quality personnel, our ability to pursue our growth strategy will be limited.

We expect to expand our clinical development and regulatory capabilities and potentially implement sales, marketing and distribution capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

As of December 31, 2022 December 31, 2023 we had 42 68 full-time employees engaged in research and development activities. employees. As our development progresses, we expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of clinical product development, regulatory affairs, manufacturing and, if any of our product candidates receives marketing approval, compliance, sales, marketing and distribution. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the

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expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

We face substantial competition, which may result in others discovering, developing or commercializing products more quickly or marketing them more successfully than us.

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The development and commercialization of new products is highly competitive. We expect to compete in the segments of the pharmaceutical, biotechnology and other related markets that pursue immuno-oncology oncology treatments. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize

products that are safer, more effective, have fewer or less severe side effects, are more convenient, or are less expensive than any products that we may develop. Our competitors also may obtain regulatory approval from the FDA or other comparable foreign regulatory authorities for their products more rapidly than we may obtain approval for ours, if ever, which could result in our competitors establishing a strong market position before we are able to enter the market or make our development more complicated. Moreover, with the proliferation of new drugs and therapies into oncology, we expect to face increasingly intense competition as new technologies become available. If we fail to stay at the forefront of technological change, we may be unable to compete effectively. Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future. The highly competitive nature of and rapid technological changes in the biotechnology and pharmaceutical industries could render our product candidates or our technology obsolete, less competitive or uneconomical.

Other products in a similar class as some of our product candidates have already been approved and other products in the same class are further along in development. As more product candidates within a particular class of biopharmaceutical products proceed through clinical development to regulatory review and approval, the amount and type of clinical data that may be required by regulatory authorities may increase or change. Consequently, the results of our clinical trials for product candidates in those classes will likely need to show a risk benefit profile that is competitive with or more favorable than those products and product candidates in order to obtain marketing approval or, if approved, a product label that is favorable for commercialization. If the risk benefit profile is not competitive with those products or product candidates, we may have developed a product that is not commercially viable, that we are not able to sell profitably or that is unable to achieve favorable pricing or reimbursement. In such circumstances, our future product revenue and financial condition would be materially and adversely affected.

Specifically, there are many companies that have commercialized or are developing immuno-oncology treatments for cancer including large pharmaceutical and biotechnology companies such as Amgen Inc. (Amgen), AstraZeneca plc (AstraZeneca) and its subsidiary, MedImmune, LLC (MedImmune), Bristol-Myers Squibb Company (BMS), Merck, Novartis AG (Novartis), Pfizer Inc. (Pfizer), Moderna, Regeneron, and F. Hoffman-La Roche AG (Roche), and Roche's subsidiary Genentech, Inc. (Genentech).

In melanoma specifically, the dominant market players are nivolumab, marketed by BMS and Ono, Pharmaceutical Co., Ltd. (Ono), combination of nivolumab & ipilimumab, marketed by BMS and Ono, combination of nivolumab and relatlimab (LAG-3 blocking antibody) marketed by BMS and pembrolizumab, marketed by Merck. We are also aware of several companies testing their compounds in combination with nivolumab or pembrolizumab. Select programs in late In mid stage development include lymphocyte activation gene-3 (LAG-3) assets from BMS (relatlimab) there is Moderna and modified interleukin-2 (IL-2) assets from Nektar Therapeutics bempegaldesleukin). Merck with an investigational personalized mRNA cancer vaccine, in combination with pembrolizumab and Regeneron testing their fianlimab anti-LAG3 in combination cmiplimab Anti-PD-1 in first line melanoma. In earlier stage development there are also BioNTech SE (BioNTech) with NEO-PV-01 and Karyopharm Therapeutics, Inc. (Karyopharm) with selinexor.

Many of our competitors, either alone or with their collaboration partners, have significantly greater financial resources and expertise in research and development, preclinical testing, clinical trials, manufacturing and marketing than we do. Future collaborations and mergers and acquisitions may result in further resource concentration among a smaller number of competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors will also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and subject registration for clinical trials, as well as in acquiring technologies complementary to, or that maybe necessary for, our programs.

The key competitive factors affecting the success of all of our programs are likely to be efficacy, safety, and convenience. If we are not successful in developing, commercializing and achieving higher levels of reimbursement than our competitors, we will not be able to compete against them and our business would be materially harmed.

The tax authorities in the jurisdictions in which we operate may challenge our transfer pricing procedures.

We are a multinational business that operates in Denmark and other tax jurisdictions, and the tax laws of those jurisdictions generally require that royalty and other payments between affiliated companies in different jurisdictions be the

same as those between unrelated companies dealing at arm's length, and that such prices are supported by contemporaneous documentation. While we believe that we operate in compliance with applicable transfer pricing laws and intend to continue to do so, our transfer pricing procedures are not binding on applicable tax authorities. If tax authorities in any of these jurisdictions were to successfully challenge our transfer prices as not reflecting arm's length transactions, they could require us to adjust our transfer prices and thereby reallocate our income or deductions to reflect these revised transfer prices, which could result in a higher overall tax liability to us and possibly interest and penalties.

Additionally, tax authorities in the jurisdictions in which we operate may challenge our treatment of the Corporate Reorganization. our corporate reorganization. No assets (either physical or intangible) were transferred from Denmark to the U.S. pursuant to the Corporate Reorganization, our corporate reorganization, nor are were any existing business functions or units operating from Denmark being transferred from IO Biotech ApS to IO Biotech, Inc. as part of the Corporate Reorganization corporate reorganization to form part of our U.S. operations. Accordingly, we did not intend to treat the Corporate Reorganization corporate reorganization as a deemed sale of all or part of our business by IO Biotech ApS to IO Biotech, Inc. If Danish tax authorities were to disagree with our position and treat the Corporate Reorganization corporate reorganization or any of our activities thereafter as a deemed sale, in whole or in part, of intellectual property rights and/or other assets owned by IO Biotech ApS to IO Biotech, Inc., we could be subject to a Danish tax, the current rate

of which is 22%, on the gain realized calculated as the difference between the fair market value and the tax value of the assets, at the time of the deemed sale of the assets from Denmark as determined by the Danish tax authorities.

Finally, the nature of our operations can produce conflicting claims from tax authorities in different countries as to the profits to be taxed in the individual countries. The jurisdictions in which we operate have double tax treaties with other jurisdictions, which provide a framework for mitigating the impact of double taxation on our revenues and capital gains. However, mechanisms developed to resolve such conflicting claims are largely untested, can be expected to be very lengthy, and do not always contain a mandatory dispute resolution clause. In recent years, tax authorities around the world have increased their scrutiny of company tax filings, and have become more rigid in exercising any discretion they may have.

In general, tax reform efforts, including with respect to transfer pricing, will require us to continually assess our organizational structure and could lead to an increased risk of international tax disputes, an increase in our effective tax rate and an adverse effect on our financial condition.

We have net operating losses to be carried forward, which may become devalued if we do not generate sufficient future taxable income, applicable corporate tax rates are reduced or if we experience an ownership change.

Our total gross deferred tax assets as of December 31, 2022 December 31, 2023 were $35.6 million $58.4 million. Total gross deferred tax assets is comprised of $32.8 million $53.3 million, $2.2 million $4.5 million and $0.6 million relating to IO Biotech ApS, IO Bio US, Inc. and IO Biotech, Inc., respectively. Our anticipated activities are also expected to result in future significant net operating losses in Denmark resulting in additional deferred tax assets. Utilization of most deferred tax assets is dependent on generating sufficient future taxable income in the appropriate jurisdiction and/or entity. The company has provided a valuation allowance of $32.7 million, $1.7 million ($53.1) million, $(4.3) million and $0.6 million $(0.5) million on our net deferred tax assets in IO Biotech ApS, IO Bio US, Inc. and IO Biotech, Inc., respectively, as of December 31, 2022 December 31, 2023. Based on all available evidence, it is considered more likely than not that all the recorded deferred tax assets will not be realized in a future period. Additionally, most of our deferred tax assets are determined by reference to applicable corporate income tax rates in Denmark and the U.S.. United States. Accordingly, in the event of a reduction of any such corporate income tax rates, the carrying value of certain of our deferred tax assets would decrease.

Moreover, our ability to use our net operating losses and other deferred tax assets to offset future taxable income in Denmark and the U.S. may be limited if we experience an ownership change. We may experience ownership changes in the future as a result of our IPO or subsequent shifts in our stock ownership, some of which are outside the Company's control.

For Danish income tax purposes, an ownership change will generally occur when one, or several shareholders together, at once or successively, acquire shares representing more than 50 percent of the share capital or voting power. Although such an ownership change entails no reduction of the amount of net operating losses to be carried forward, the utilization is restricted to exclude offsetting against positive net capital income (e.g. income from interest, dividend and royalty) on net operating losses incurred in a previous income year, where the ownership differs by 50 percent (under section 12D of the Danish Corporate Tax Act). The restriction may limit future offsetting against net operating profits, when the ownership change is due to the listing on an exchange.

For U.S. federal income tax purposes, an ownership change will generally occur when the percentage of our stock (by value) owned by one or more "5% shareholders" (as defined in the U.S. Internal Revenue Code of 1986, as amended) has increased by more than 50% over the lowest percentage owned by such shareholders at any time during the prior three years (calculated on a rolling basis). We anticipate that we will incur losses in the United States in the foreseeable future related to

our research and development activities. Due to potential ownership changes under Section 382 of the Code, we may be limited in our ability to realize a tax benefit from the use of such losses, whether or not we attain profitability in future years.

In addition, our ability to utilize any future net operating losses may be limited by Pub. L. 115-97, enacted in 2017 and commonly known as the Tax Cuts and Jobs Act of 2017 (TCJA). Under the TCJA, the amount of our net operating losses that we are permitted to deduct in any taxable year is limited to 80% of our taxable income in such year, where taxable income is determined without regard to the net operating loss deduction itself, while allowing unused net operating losses to be carried forward indefinitely.

For these reasons, a material devaluation in our deferred tax assets due to insufficient taxable income, lower corporate income tax rates or ownership change would have an adverse effect on our results of operations and financial condition.

We may be subject to current taxation on some of the income of our foreign subsidiaries even absent any cash distributions.

Because we hold directly or indirectly all of the shares of our foreign subsidiaries, including IO Biotech ApS, such subsidiaries are treated as controlled foreign corporations (CFC) for U.S. federal income tax purposes. For U.S. federal income tax purposes, IO Biotech, Inc. will therefore need to include in its taxable income each year its "global intangible low-taxed income" and IO Biotech ApS's "subpart F income," if any, even if no distributions are made.

Our foreign subsidiaries may directly become subject to U.S. federal income tax and be subject to a branch profits tax in the United States, which could reduce our after-tax returns and the value of our shares.

We currently intend to conduct substantially all of our businesses and operations in a manner such that our foreign subsidiaries will not be treated as engaged in a trade or business in the United States and will not be subject to additional U.S. income tax or branch profits tax. However, it is not entirely clear when a foreign subsidiary is treated as being engaged in a trade or business in the United States for U.S. federal income tax purposes. Accordingly, we cannot assure you that the Internal Revenue Service (IRS) will not contend, perhaps successfully, that our foreign subsidiaries were engaged in a trade or business in the United States or are subject to more U.S. income tax than they currently incur. A foreign corporation deemed to be so engaged would be subject to U.S. federal income tax on its income that is treated as effectively connected with the conduct of that trade or business, as well as to branch profits tax on its "dividend equivalent amount," unless the corporation is entitled to relief under an applicable tax treaty, which is determined on an annual basis.

Our business operations and current and future relationships with investigators, health care professionals, consultants, third-party payors and customers are subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, transparency laws and other healthcare laws and regulations. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

Healthcare providers and others play a primary role in the recommendation and prescription of any products for which we obtain marketing approval. Although we do not currently have any products on the market, our operations and current and future arrangements with investigators, healthcare professionals, customers and third-party payors, may be subject to various U.S. federal and state healthcare laws and regulations, including, without limitation, the U.S. federal Anti-Kickback Statute, the U.S. federal civil and criminal false claims laws and the Physician Payments Sunshine Act and regulations. These laws may impact, among other things, our current business operations, including our clinical research activities, and proposed sales, marketing and education programs and constrain the business of financial arrangements and relationships with healthcare providers and other parties through which we may market, sell and distribute our products for which we obtain marketing approval. In addition, we may be subject to additional healthcare, statutory and regulatory requirements and enforcement by foreign regulatory authorities in jurisdictions in which we conduct our business. See Part I, Item 1, "Government Regulations – Other Regulatory Matters – Other Healthcare Laws" for additional detail.

Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices, including certain arrangements with physicians who receive stock, warrants or stock options as compensation for services provided to us, do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, exclusion from U.S. government funded healthcare programs, such as Medicare and Medicaid, or similar programs in other countries or jurisdictions, disgorgement, imprisonment, contractual damages, reputational harm, diminished profits, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of

non-compliance with these laws and the delay, reduction, termination or restructuring of our operations. Further, defending against any such actions can be costly and time-consuming, and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. If any of the above occur, it could adversely affect our ability to operate our business and our results of operations.

Healthcare legislative reform measures may have a material adverse effect on our business and results of operations operations.

The United States and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system that could prevent or delay marketing approval of our current product candidates and any future product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell a product for which we obtain marketing approval. Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example: (1) changes to our manufacturing arrangements; (2) additions or modifications to product labeling; (3) the recall or discontinuation of our products; or (4) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business.

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, in March 2010, the ACA was passed, which substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacted the U.S. pharmaceutical industry. The ACA, among other things, subjected biological products to potential competition by lower-cost biosimilars, addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs and biologics that are inhaled, infused, instilled, implanted or injected, and increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program, and extended the rebate program to individuals enrolled in Medicaid managed care organizations, and established annual fees and taxes on manufacturers of certain branded prescription drugs and biologics.

Since its enactment, there have been judicial, executive and Congressional challenges to certain aspects of the ACA. See Part I, Item 1, “Government Regulation – Healthcare Reform” for additional detail on recent challenges to the ACA.

We expect that the ACA, new laws, and other healthcare reform measures that may be adopted in the future may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and additional downward pressure on the price that we receive for any approved product. 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. We cannot predict the initiatives that may be adopted in the future. If we or any third parties we may engage are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or such third parties are not able to maintain regulatory compliance, our product candidates may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability.

Upcoming changes in the pharmaceutical product legislation in certain jurisdictions may have an adverse effect on the data and market exclusivity available for our products.

The EU Pharma Law Review initiated by the European Commission on April 6, 2023 could have a significant impact on the RDP available for innovative medicinal products in the EU. If adopted in current form, the EU Pharma Law Proposal would reduce the current baseline for data exclusivity from eight to six years, extendable under certain conditions. Such RDP reduction could lead to faster access to the EU market for generics and biosimilars.

The EU Pharma Law Proposal also proposes changes the current orphan market exclusivity approach. If adopted in the current form, the EU Pharma Law Proposal would in most cases reduce the duration of orphan market exclusivity.

We are subject to a variety of privacy and data security laws, and our failure to comply with them could harm our business.

We maintain a large quantity of sensitive information, including confidential business and personal information in connection with the conduct of our clinical trials and related to our employees, and we are subject to laws and regulations governing the privacy and security of such information. In the United States, there are numerous federal and state privacy and data security laws and regulations governing the collection, use, disclosure and protection of personal information, including federal and state health information privacy laws, federal and state security breach notification laws, and federal and state consumer protection laws. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing focus on privacy and data protection issues, including with respect to regulatory enforcement and private litigation, which may affect our business and is expected to increase our compliance costs and exposure to liability. In the United States, numerous federal and state laws and regulations could apply to our operations or the operations of our partners, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws and regulations (e.g., Section 5 of the Federal Trade Commission (FTC) Act), that govern the collection, use, disclosure, and protection of health-related and other personal information. In addition, we may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are may be subject to privacy and security requirements under HIPAA, as amended by HITECH and regulations promulgated thereunder. Depending on the facts and circumstances, we could be subject to significant penalties if we obtain, use, or disclose, or are subject to an actual or alleged data breach regarding, individually identifiable health information in a manner that is not authorized or permitted by HIPAA. In 2023, the SEC finalized rules requiring enhanced disclosures regarding cybersecurity risk management, strategy, and governance, as well as the timely reporting of material cybersecurity incidents. These rules mandate disclosures about our processes for identifying, assessing, and managing cybersecurity risks, the role of management and the board of directors in overseeing these risks, and specific incidents that materially affect us.

In the EEA, we are subject to the EU GDPR, which took effect in May 2018. The EU GDPR governs the collection, use, disclosure, transfer or other processing of personal data (i.e., data which identifies an individual or from which an individual is identifiable), including clinical trial data, and grants individuals various data protection rights (e.g., the right to erasure of

personal data). The EU GDPR imposes a number of obligations on companies, including inter alia: (1) accountability and transparency requirements, and enhanced requirements for obtaining valid consent; (2) obligations to consider data protection as any new products or services are developed and to limit the amount of personal data processed; (3) obligations to implement appropriate technical and organizational measures to safeguard personal data and to report certain personal data breaches to the supervisory authority without undue delay (and no later than 72 hours where feasible); and (4) additional, more onerous requirements around the processing of special categories of personal data (including health data and genetic data). In addition, the EU GDPR prohibits the transfer of personal data from the EEA to the United States and other jurisdictions that the European Commission does not recognize as having “adequate” data protection laws unless a data transfer mechanism has been put in place. In July 2020, the Court of Justice of the EU (CJEU) in the Schrems II decision limited how organizations could lawfully transfer personal data from the EEA to the United States by invalidating the EU-US Privacy Shield for purposes of international transfers and imposing further restrictions on use of the standard contractual clauses (SCCs), including a requirement for companies to carry out a transfer impact assessment, which among other things, assesses laws governing access to personal data in the recipient country and considers whether supplementary measures that

provide privacy protections additional to those provided under SCCs will need to be implemented to ensure an essentially equivalent level of data protection to that afforded in the EEA. The European Commission subsequently issued new SCCs in June 2021 to account for the decision of the CJEU and recommendations made by the European Data Protection Board and which are in turn relatively more onerous. At present, there are few, if any, viable alternatives to the SCCs. However, on October 7, 2022, the Biden administration introduced an Executive Order to facilitate a new Trans-Atlantic Data Privacy Framework which will act as a successor to the invalidated EU-US Privacy Shield. On December 13, 2022, the European Commission also published its draft adequacy decision to reflect its view that the new Executive Order and Trans-Atlantic Data Privacy Framework, is able to meet the concerns raised in Schrems II. If the draft adequacy decision is approved and implemented, the agreement will facilitate the transatlantic flow of personal data and provide additional safeguards to data transfer mechanisms (including SCCs and Binding Corporate Rules) for companies transferring personal data from the EU to the US. However, before parties rely on the new framework, there are still legislative and regulatory steps that must be undertaken both in the US and in the EU. The EU GDPR imposes substantial fines for breaches and violations (up to the greater of €20 million or 4% of consolidated annual worldwide gross revenue), and confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies and obtain compensation for damages resulting from violations of the EU GDPR. The EU GDPR increases our responsibility and liability in relation to personal data that we process, and additional mechanisms put in place to address compliance with the EU GDPR must be kept under review as the legislative and regulatory landscape for data protection in the EU continues to evolve.

Relatedly, following Brexit, the EU GDPR has been implemented in the United Kingdom (as the UK GDPR). The UK GDPR sits alongside the UK Data Protection Act 2018 which implements certain derogations in the EU GDPR into UK law. Under the UK GDPR, companies not established in the UK but that process personal data in relation to the offering of goods or services to individuals in the UK, or to monitor their behavior will be subject to the UK GDPR – the requirements of which are (at this time) largely aligned with those under the EU GDPR and as such, may lead to similar compliance and operational costs with potential fines of up to £17.5 million or 4% of global turnover. The UK Government has published its own form of SCCs, known as the International Data Transfer Agreement (the "IDTA") (IDTA) and International Data Transfer Addendum (UK Addendum) to the EU SCCs. The UK Information Commissioner's Office (the "ICO") (ICO) has also published its own version of the transfer impact assessment and recently revised guidance on international transfers, although entities may choose to adopt either the EU or UK style transfer impact assessment. In terms of international data transfers between the UK and US, it is understood that the UK and the US are also negotiating an adequacy agreement.

Compliance with these and any other applicable privacy and data security laws and regulations is a rigorous and time-intensive process, and we may be required to devote additional resources to and put in place additional mechanisms ensuring compliance with the new data protection and disclosure rules. Despite our efforts to comply with these laws and regulations, the inherent complexity of data security and cyber threats, and the newness of some of these requirements, such as the SEC's cybersecurity disclosure requirements, present a risk of non-compliance or insufficient disclosure, which could invite regulatory scrutiny and affect our operational and financial performance. Furthermore, the laws are not consistent, and compliance in the event of a widespread data breach is costly. In addition, states are constantly adopting new laws or amending existing laws, requiring attention to frequently changing regulatory requirements. For example, California enacted the California Consumer Privacy Act (the CCPA), which took effect on January 1, 2020, became enforceable by the California Attorney General on July 1, 2020, and was the first comprehensive state privacy law in the United States. The CCPA gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing and receive detailed information about how their personal information is used by requiring covered companies to provide new disclosures to California consumers (as that term is broadly defined) and provide such consumers new ways to opt-out of certain sales of personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. Further, the California Privacy Rights Act (the CPRA), which further amended the CCPA, went into effect on January 1, 2023. The CCPA, as amended by the CPRA, imposes additional data protection obligations on companies doing business in California, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. It will also create a new California data protection agency authorized to

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issue substantive regulations and could result in increased privacy and information security enforcement. The majority of the provisions will go went into effect on January 1, 2023, and additional compliance investment and potential business process changes may be required. Although the CCPA currently exempts certain health-related information, including clinical trial data, the CCPA (as amended by the CPRA) may increase our compliance costs and potential liability. Similar laws have been adopted in other states (for example Nevada, Virginia and Colorado) or proposed in other states and at the federal level, and if passed, such laws may have potentially conflicting requirements that would make compliance challenging. For example, on March 2, 2021, the Nevada Privacy of Information Collected on the Internet from Consumers Act went into effect on October 1, 2021, the Virginia Consumer Data Protection Act went into effect on January 1, 2023, the Colorado Privacy Act goes went into effect on July 1, 2023, the Connecticut Data Privacy Act goes went into effect July 1, 2023, and the Utah Consumer Privacy Act goes went into effect December 31, 2023. Additionally, newly introduced state laws related to health privacy may result in additional compliance costs. For example, the state of Washington recently passed the "My Health My Data" Act, which will regulate "consumer health data," defined as "personal information that is linked or reasonably linkable to a consumer and that identifies a consumer's past, present, or future physical or mental health." The "My Health My Data" Act provides exemptions for personal data used or shared in research, including data subject to 45 C.F.R. Parts 46, 50, and 56. Additionally, Nevada recently enacted a consumer health data privacy bill, and other states could adopt health-specific privacy laws that could impact our business.

The Federal Trade Commission (FTC) and many state attorneys general are interpreting existing federal and state consumer protection laws to impose evolving standards for the collection, use, dissemination and security of health-related and other personal information. For instance, the FTC has promulgated standards for fair information practices, which concern consumer notice, choice, security and access, and also require notice of certain health information breaches outside the HIPAA context. Privacy laws require us to publish statements that describe how we handle personal information and choices individuals may have about the way we handle their personal information. Violating individuals' privacy rights, publishing false or misleading information about security practices, or failing to take appropriate steps to keep individuals' personal information secure may constitute unfair or deceptive acts or practices in violation of Section 5 of the FTC Act. Additionally, the FTC recently published an advance notice of proposed rulemaking on commercial surveillance and data security in 2022 and is seeking comment on whether it should may implement new trade regulation rules or other regulatory alternatives concerning the ways in which companies (1) collect, aggregate, protect, use, analyze, and retain consumer data, as well as (2) transfer, share, sell, or otherwise monetize that data in ways that are unfair or deceptive. deceptive in the coming years. Federal regulators, state attorneys general and plaintiffs' attorneys have been and will likely continue to be active in this space, and if we do not comply with existing or new laws and regulations related to patient health information, we could be subject to criminal or civil sanctions.

Any actual or perceived failure by us to comply with applicable privacy and data security laws and regulations could result in regulatory investigations, reputational damage, orders to cease/ change our processing of our data, enforcement notices, and/ or assessment notices (for a compulsory audit). We may also face civil claims including representative actions and other class action type litigation (where individuals have suffered harm), potentially amounting to significant compensation or damages liabilities, as well as associated costs, diversion of internal resources, and reputational harm.

Risks Related to Intellectual Property

If we are unable to obtain and maintain sufficient intellectual property protection for our platform technologies and product candidates, or if the scope of the intellectual property protection is not sufficiently broad, our competitors could develop and commercialize products similar or identical to ours, and our ability to successfully commercialize our products may be adversely affected.

We rely upon a combination of patents, know-how and confidentiality agreements to protect the intellectual property related to our products and technologies and to prevent third parties from copying and surpassing our achievements, thus eroding our competitive position in our market.

Our success depends in large part on our ability to obtain and maintain patent protection for our T-win technology T-win® platform, product candidates and their uses, as well as our ability to operate without infringing the proprietary rights of others. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our novel discoveries and technologies that are important to our business. We cannot guarantee that our pending and future patent applications will result in patents being issued or that issued patents will afford sufficient protection of our product candidates or their intended uses against competitors, nor can there be any assurance that the patents issued will not be infringed, designed around, invalidated by third parties, or that they will effectively prevent others from commercializing competitive technologies, products or product candidates.

Obtaining and enforcing patents is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications or maintain and/or enforce patents that may issue based on our patent applications, at a reasonable cost or in a timely manner, including delays as a result of the COVID-19 pandemic impacting our or our licensors' operations. manner. It is also possible that we will fail to identify patentable aspects of our research and development results before it is too late to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to patentable aspects of our research and development output, such as our employees, corporate

collaborators, outside scientific collaborators, contract research organizations, contract manufacturers, CROs, CMOs, consultants, advisors and other third parties, any of these parties may breach these agreements and disclose such results before a patent application is filed, thereby jeopardizing our ability to seek patent protection.

Composition of matter patents for biological and pharmaceutical product candidates often provide a strong form of intellectual property protection for those types of products, as such patents provide protection without regard to any method of use. However, we cannot be certain that the claims in our pending patent applications directed to

composition of matter of our product candidates will be considered patentable by the United States Patent and Trademark Office (USPTO) or by patent offices in foreign countries, or that the claims in any of our issued patents will be considered valid and enforceable by courts in the United States or foreign countries. Method of use patents protect the use of a product for the specified method. This type of patent does not prevent a competitor from making and marketing a product that is identical to our product for an indication that is outside the scope of the patented method. Moreover, even if competitors do not actively promote their product for our targeted indications, physicians may prescribe these products "off-label." Although off-label prescriptions may infringe or contribute to the infringement of method of use patents, the practice is common and such infringement is difficult to prevent or prosecute.

The patent position of biopharmaceutical companies generally is highly uncertain, involves complex legal, scientific, and factual questions and has in recent years been the subject of much litigation, resulting in court decisions, including United States Supreme Court decisions, which have increased uncertainties as to the ability to enforce patent rights in the future. The standards that the USPTO and its foreign counterparts use to grant patents are not always applied predictably or uniformly. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States, or vice versa.

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our potential future collaborators will be successful in protecting our product candidates by obtaining and defending patents. For example, we may not be aware of all third-party intellectual property rights potentially relating to our product candidates or their intended uses, and as a result the impact of such third-party intellectual property rights upon the patentability of our own patents and patent applications, as well as the impact of such third-party intellectual property upon our freedom to operate, is highly uncertain. Patent applications in the United States and other jurisdictions are typically not published until 18 months after filing or, in some cases, not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions. As a result, the issuance, inventorship, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending patent applications may be challenged in patent offices in the United States and abroad. The issuance of a patent is not conclusive as to its inventorship, ownership, scope, validity or enforceability. Even issued patents may later be found invalid or unenforceable or may be modified or revoked in proceedings instituted by third parties before various patent offices or in courts. For example, our pending patent applications may be subject to third-party pre-issuance submissions of prior art to the USPTO or our issued patents may be subject to post-grant review (PGR) proceedings, oppositions, derivations, reexaminations, interference or *inter partes* review proceedings, in the United States or elsewhere, challenging our patent rights or the patent rights of others. An adverse determination in any such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated, or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. In addition, given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. The degree of future protection for our proprietary rights is uncertain. Only limited protection may be available and may not adequately protect our rights or permit us to gain or keep any competitive advantage. Any failure to obtain or maintain patent protection with respect to our product candidates or their uses could have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable, processes for which patents are difficult to enforce and any other elements of our discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. We may also rely on trade secret protection as temporary protection for concepts that may be included in a future patent filing. However, trade secret protection will not protect us from innovations that a competitor develops independently of our proprietary know how. If a competitor independently develops a technology that we protect as a trade secret and files a patent application on that technology, then we may not be able to patent that technology in the future, may require a license from the competitor to use our own know-how, and if the license is not available on commercially-viable terms, then we may not be able to launch our product. Although we require all of our employees to assign their inventions to us, and require all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology to enter into confidentiality agreements, we cannot be certain that our trade secrets and other confidential proprietary

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information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Furthermore, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent unauthorized material disclosure of our intellectual property to third parties, we will not be able to establish or maintain a competitive advantage in our market, and this scenario could materially adversely affect our business, financial condition and results of operations.

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

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

- others may be able to make product candidates that are the same as or similar to ours but that are not covered by the claims of the patents that we own or have excl licensed;
- we or our licensors or future collaborators might not have been the first to make the inventions covered by the issued patent or pending patent application that we have exclusively licensed;
- we or our licensors or future collaborators might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that noncompliance with the USPTO and foreign governmental patent agencies requirement for a number of procedural, documentary, fee payment an provisions during the patent process can result in abandonment or lapse of a patent or patent application, and partial or complete loss of patent rights in the re jurisdiction;
- it is possible that our pending patent applications will not lead to issued patents;
- issued patents that we own or have exclusively licensed may be revoked, modified, or held invalid or unenforceable, as a result of legal challenges by our competitors
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such ac to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- we cannot predict the scope of protection of any patent issuing based on our patent applications, including whether the patent applications that we own or in-licer result in issued patents with claims that directed to our product candidates or uses thereof in the United States or in other foreign countries;
- there may be significant pressure on the U.S. government and international governmental bodies to limit the scope of patent protection both inside and outside the States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns;
- countries other than the United States may have patent laws less favorable to patentees than those upheld by U.S. courts, allowing foreign competitors a better oppo to create, develop and market competing product candidates;

- the claims of any patent issuing based on our patent applications may not provide protection against competitors or any competitive advantages, or may be challen third parties;
- if enforced, a court may not hold that our patents are valid, enforceable and infringed;
- we may need to initiate litigation or administrative proceedings to enforce and/or defend our patent rights which will be costly whether we win or lose;
- we may choose not to file a patent application in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent application co such intellectual property;
- we may fail to adequately protect and police our trademarks and trade secrets; and

- the patents of others may have an adverse effect on our business, including if others obtain patents claiming subject matter similar to or improving that covered patents and patent applications.

Should any of these or similar events occur, they could significantly harm our business, results of operations and prospects.

If we fail to comply with our obligations imposed by any intellectual property licenses with third parties that we may need in the future, we could lose rights that are important to our business.

We may in the future require licenses to third-party technology and materials. Such licenses may not be available in the future or may not be available on commercially reasonable terms, or at all, which could have a material adverse effect on our business and financial condition. We may rely on third parties from whom we license proprietary technology to file and prosecute patent applications and maintain patents and otherwise protect the intellectual property we license from them. We may have limited control over these activities or any other intellectual property that may be related to our in-licensed intellectual property. For example, we cannot be certain that such activities by these licensors will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights. We may have limited control over the manner in which our licensors initiate an infringement proceeding against a third-party infringer of the intellectual property rights, or defend certain of the intellectual property that may be licensed to us. It is possible that the licensors' infringement proceeding or defense activities may be less vigorous than if we conduct them ourselves. Even if we acquire the right to control the prosecution, maintenance and enforcement of the licensed and sublicensed intellectual property relating to our product candidates, we may require the cooperation of our licensors and any upstream licensor, which may not be forthcoming. Therefore, we cannot be certain that the prosecution, maintenance and enforcement of these patent rights will be in a manner consistent with the best interests of our business. If we or our licensor fail to maintain such patents, or if we or our licensor lose rights to those patents or patent applications, the rights we have licensed may be reduced or eliminated and our right to develop and commercialize any of our product candidates that are the subject of such licensed rights could be adversely affected. In addition to the foregoing, the risks associated with patent rights that we license from third

parties will also apply to patent rights we may own in the future. Further, if we fail to comply with our diligence, development and commercialization timelines, milestone payments, royalties, insurance and other obligations under our license agreements, we may lose our patent rights with respect to such agreement, which would affect our patent rights worldwide.

Termination of our current or any future license agreements would reduce or eliminate our rights under these agreements and may result in our having to negotiate new or reinstated agreements with less favorable terms or cause us to lose our rights under these agreements, including our rights to important intellectual property or technology. Any of the foregoing could prevent us from commercializing our other product candidates, which could have a material adverse effect on our operating results and overall financial condition.

In addition, intellectual property rights that we may in-license in the future may be sublicenses under intellectual property owned by third parties, in some cases through multiple tiers. The actions of our licensors may therefore affect our rights to use our sublicensed intellectual property, even if we are in compliance with all of the obligations under our license agreements. Should our licensors or any of the upstream licensors fail to comply with their obligations under the agreements pursuant to which they obtain the rights that are sublicensed to us, or should such agreements be terminated or amended, our ability to develop and commercialize our product candidates may be materially harmed.

In the future, we may need to obtain additional licenses of third-party technology that may not be available to us or are available only on commercially unreasonable terms, and which may cause us to operate our business in a more costly or otherwise adverse manner that was not anticipated.

We currently own intellectual property directed to our product candidates and other proprietary technologies, including our T-win technology T-win® platform. Other pharmaceutical companies and academic institutions may also have filed or are planning to file patent applications potentially relevant to our business. From time to time, in order to avoid infringing these third-party patents, we may be required to license technology from additional third parties to further develop or commercialize our product candidates. Should we be required to obtain licenses to any third-party technology, including any such patents required to manufacture, use or sell our product candidates, such licenses may not be available to us on commercially reasonable terms, or at all. The inability to obtain any third-party license required to develop or commercialize any of our product candidates could cause us to abandon any related efforts, which could seriously harm our business and operations.

The licensing or acquisition of third-party intellectual property rights is a competitive area, and several more established companies may pursue strategies to license or acquire third-party intellectual property rights 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. Even if we are able to obtain a license under such intellectual property rights, any such license may be non-exclusive, which may allow our competitors to access the same technologies licensed to us.

Moreover, some of our owned and in-licensed patents or patent applications or future patents may be co-owned with third parties. If we are unable to obtain an exclusive license to any such third-party co-owners' interest in such patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co-owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us. Furthermore, our owned and in-licensed patents maybe subject to a reservation of rights by one or more third parties. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

If we are sued for infringing intellectual property rights of third parties, such litigation could be costly and time consuming and could prevent or delay us from developing or commercializing our product candidates.

Our commercial success depends, in part, on our ability to develop, manufacture, market and sell our product candidates without infringing the intellectual property and other proprietary rights of third parties. Third parties may allege that we have infringed, misappropriated or otherwise violated their intellectual property. Litigation or other legal proceedings relating to intellectual property claims, with or without merit, is unpredictable and generally expensive and time consuming and, even if resolved in our favor, is likely to divert significant resources from our core business, including distracting our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the market price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. 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. In addition, patent holding companies that focus solely on extracting royalties and settlements by enforcing patent rights may target us.

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There is a substantial amount of intellectual property litigation in the biotechnology and pharmaceutical industries, and we may become party to, or threatened with, litigation or other adversarial proceedings regarding intellectual property rights with respect to our product candidates. We cannot be certain that our product candidates and other proprietary technologies we may develop will not infringe existing or future patents owned by third parties. Third parties may assert infringement claims against us based on existing or future intellectual property rights. If we are found to infringe a third party's intellectual property rights, we could be forced, including by court order, to cease developing, manufacturing or commercializing the infringing candidate product or product. Alternatively, we may be required to obtain a license from such third party in order to use the infringing technology and continue developing, manufacturing or marketing the infringing candidate product or product. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our investigational products or force us to cease some of our business operations, which could materially harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business.

We cannot guarantee that any of our or our licensors' patent searches or analyses, including but not limited to the identification of relevant patents, analysis of the scope of relevant patent claims or determination of the expiration of relevant patents, are complete or thorough. We may not be aware of patents that have already been issued and that a third party, for example, a competitor in the fields in which we are developing our product candidates, might assert are infringed by our current or future product candidates, including claims to compositions, formulations, methods of manufacture or methods of use or treatment that cover our product candidates. It is also possible that patents owned by third parties of which we are aware, but which we do not believe are relevant to our product candidates and other proprietary technologies we may develop, could be found to be infringed by our product candidate. In addition, because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that our product candidates may infringe. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our product candidates or the use of our product candidates. . Our determination of the expiration date

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of any patent in the United States, Europe or elsewhere that we consider relevant may be incorrect, which may negatively impact our ability to develop and market our product candidates. Our competitors in both the United States and abroad, many of which have substantially greater resources and have made substantial investments in patent portfolios and competing technologies, may have applied for or obtained or may in the future apply for and obtain, patents that will prevent, limit or otherwise interfere with our ability to make, use and sell our product candidates. The pharmaceutical and biotechnology industries have produced a considerable number of patents, and it may not always be clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we were sued for patent infringement, we would need to demonstrate that our product candidates, products or methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid or unenforceable, and we may not be able to do this. Proving invalidity may be difficult. For example, in the United States, proving invalidity in court requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents, and there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent. Even if we are successful in these proceedings, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted in pursuing these proceedings, which could have a material adverse effect on our business and operations. 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 litigation. In addition, we may not have sufficient resources to bring these actions to a successful conclusion.

We may choose to challenge the enforceability or validity of claims in a third party's U.S. patent by requesting that the USPTO review the patent claims in an *ex-parte* re-exam, *inter partes* review or post-grant review proceedings. These proceedings are expensive and may consume our time or other resources. We may choose to challenge a third party's patent in patent opposition proceedings in the European Patent Office (EPO), or other foreign patent office. The costs of these opposition proceedings could be substantial, and may consume our time or other resources. If we fail to obtain a favorable result at the USPTO, EPO or other patent office then we may be exposed to litigation by a third party alleging that the patent may be infringed by our product candidates or proprietary technologies.

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

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Competitors or other third parties may infringe our patents, trademarks or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming and divert the time and attention of our management and scientific personnel. Our pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents, in addition to counterclaims asserting that our patents are invalid or unenforceable, or both. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non-enablement or insufficient written description. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution. The outcome following legal assertions of invalidity and unenforceability is unpredictable. In any patent infringement proceeding, there is a risk that a court will decide that a patent of ours is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent's claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patent claims do not cover the invention, or decide that the other party's use of our patented technology falls under the safe harbor to patent infringement under 35 U.S.C. §271(e)(1). An adverse outcome in a litigation or proceeding involving our patents could limit our ability to assert our patents against those parties or other competitors and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. Any of these occurrences could adversely affect our competitive business position, business prospects and financial condition. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. 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 litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be

negative, it could have a material adverse effect on the price of shares of our common stock. Moreover, we cannot assure you that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings.

Because of the expense and uncertainty of litigation, we may not be in a position to enforce our intellectual property rights against third parties.

Because of the expense and uncertainty of litigation, we may conclude that even if a third party is infringing our issued patent, any patents that may be issued as a result of our pending or future patent applications or other intellectual property rights, the risk-adjusted cost of bringing and enforcing such a claim or action may be too high or not in the best interest of our company or our stockholders. In such cases, we may decide that the more prudent course of action is to simply monitor the situation or initiate or seek some other non-litigious action or solution.

We may be subject to claims that our employees, consultants, or independent contractors have wrongfully used or disclosed confidential information of third parties.

We employ and may employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees, consultants, or independent contractors have inadvertently or otherwise used or disclosed confidential information of our employees' former employers or other third parties. We may also be subject to claims that former employers or other third parties have an ownership interest in our future patents. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. There is no guarantee of success in defending these claims, and even if we are successful, litigation could result in substantial cost and be a distraction to our management and other employees.

Changes in patent law in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

As is the case with other biopharmaceutical companies, our success is heavily 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. Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs, and 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. Patent reform legislation in the United States and other countries, including the Leahy-Smith America Invents Act (the Leahy-Smith Act), signed into law on September 16, 2011, could increase those uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art and provide more efficient and cost-effective avenues for competitors to challenge the validity of patents. 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. Further, because of a lower evidentiary standard in these USPTO post-grant proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Thus, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

After March 2013, under the Leahy-Smith Act, the United States transitioned to a first inventor to file system in which, assuming that the other statutory requirements 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 we file an application covering the same invention, could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application, but circumstances could prevent us from promptly filing patent applications on our inventions. Since patent applications in the United States and

most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we or our licensors were the first to either (i) file any patent application related to our product candidates and other proprietary technologies we may develop or (ii) invent any of the inventions claimed in our or our licensor's patents or patent applications. Even where we have a valid and enforceable patent, we may not be able to exclude others from practicing the claimed invention where the other party can show that they used the invention in commerce before our filing date. Thus the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition, the patent positions of companies in the development and commercialization of biologics and pharmaceuticals are particularly uncertain. The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. Depending on future actions by the U.S. Congress, the U.S. courts, the USPTO and the relevant law-making bodies in other countries, 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, in the 2013 case *Assoc. for Molecular Pathology v. Myriad Genetics, Inc.*, the U.S. Supreme Court held that certain claims to DNA molecules are not patentable. While we do not believe that any of the patents owned or licensed by us will be found invalid based on this decision, we cannot predict how future decisions by the courts, the U.S. Congress or the USPTO may impact the value of our patents.

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

Periodic maintenance fees, renewal fees, annuities fees and various other governmental fees on patents and/or patent applications are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent and/or patent application. The USPTO and various foreign governmental patent agencies also require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse including due to the effect of the COVID-19 pandemic on us or our patent maintenance vendors, 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 noncompliance 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. If we fail to maintain the patents and patent applications covering our product candidates, our competitive position would be adversely affected.

Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time.

The term of any individual patent depends on applicable law in the country where the patent is granted. In the United States, provided all maintenance fees are timely paid, a patent generally has a term of 20 years from its application filing date or earliest claimed non-provisional filing date. Extensions may be available under certain circumstances, but the life of a patent and, correspondingly, the protection it affords is limited. Even if we or our licensors obtain patents covering our product candidates, when the terms of all patents covering a product expire, our business may become subject to competition from competitive medications or vaccines, including generic medications. medications or vaccines. Given the amount of time required for the development, testing and regulatory review and approval of new product candidates, patents protecting such candidates may expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

If we do not obtain patent term extension in the United States under the Hatch-Waxman Act and in foreign countries under similar legislation, thereby potentially extending the term of marketing exclusivity for our product candidates, our business may be harmed.

In the United States, a patent that covers an FDA-approved drug or biologic may be eligible for a term extension designed to restore the period of the patent term that is lost during the premarket regulatory review process conducted by the FDA. Depending upon the timing, duration and conditions of FDA marketing approval of our product candidates, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, as amended (the Hatch-Waxman Act), which permits a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years

from the date of product approval, and only claims covering such approved drug product, a method for using it or a method for manufacturing it may be extended. In Europe, our product candidates may be eligible for term extensions based on similar legislation. In either jurisdiction, however, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Even if we are granted such extension, the duration of such extension may be less than our request. If we are unable to obtain a patent term extension, or if the term of any such extension is less than our request, the period during which we can enforce our patent rights for that product will be in effect shortened and our competitors may obtain approval to market competing products sooner. The resulting reduction of years of revenue from applicable products could be substantial.

We enjoy only limited geographical protection with respect to certain patents and we may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents covering our product candidates in all countries throughout the world would be prohibitively expensive, and even in countries where we have sought protection for our intellectual property, such protection can be less extensive than those in the United States. The requirements for patentability may differ in certain countries, particularly developing countries, and the breadth of patent claims allowed can be inconsistent. 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 United States. In-licensing patents covering our product candidates in all countries throughout the world may similarly be prohibitively expensive, if such opportunities are available at all. And in-licensing or filing, prosecuting and defending patents even in only those jurisdictions in which we develop or commercialize our product candidates may be prohibitively expensive or impractical. Competitors may use our and our licensors' technologies in jurisdictions where we have not obtained patent protection or licensed patents to develop their own products and, further, may export otherwise infringing products to territories where we and our licensors have patent protection, but where enforcement is not as strong as that in the United States or Europe. These products may compete with our product candidates, and our or our licensors' patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

The laws of some jurisdictions do not protect intellectual property rights to the same extent as the laws or regulations in the United States and Europe, and many companies have encountered significant difficulties in protecting and defending proprietary rights in such jurisdictions. Moreover, the legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets or other forms of intellectual property, particularly those relating to biotechnology products, which could make it difficult for us to prevent competitors in some jurisdictions from marketing competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, are likely to result in substantial costs and divert our efforts and attention from other aspects of our business, and additionally could put at risk our or our licensors' patents at risk of being invalidated or interpreted narrowly, could increase the risk of our or our licensors' patent applications not issuing, or could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, while damages or other remedies may be awarded to the adverse party, which may be commercially significant. If we prevail, damages or other remedies awarded to us, 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. Furthermore, while we intend to protect our intellectual property rights in our expected significant markets, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our product candidates. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate,

which may have an adverse effect on our ability to successfully commercialize our product candidates in all of our expected significant foreign markets. If we or our licensors encounter difficulties in protecting, or are otherwise precluded from effectively protecting, the intellectual property rights important for our business in such jurisdictions, the value of these rights may be diminished and we may face additional competition in those jurisdictions.

In some jurisdictions, including certain European countries, compulsory licensing laws compel patent owners to grant licenses to third parties. In addition, some countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our licensors are forced to grant a license to third parties under patents relevant to our business, or if we or our licensors are prevented from enforcing patent rights against third parties, our competitive position may be substantially impaired in such jurisdictions.

We may rely on trade secret and proprietary know-how which can be difficult to trace and enforce and, if we are unable to protect the confidentiality of our trade secrets, our business and competitive position would could be harmed.

In addition to seeking patents for some of our technology and current product candidates or any future product candidates, we may also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain

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our competitive position. Elements of our current product candidates or any future product candidates, including processes for their preparation and manufacture, as well as our T-win technology T-win® platform, may involve proprietary know-how, information, or technology that is not covered by patents, and thus for these aspects we may consider trade secrets and know-how to be our primary intellectual property. Any disclosure, either intentional or unintentional, by our employees, the employees of third parties with whom we share our facilities or third party consultants and vendors that we engage to perform research, clinical trials or manufacturing activities, or misappropriation by third parties (such as through a cybersecurity breach) of our trade secrets or proprietary information could enable competitors to duplicate or surpass our technological achievements, thus eroding our competitive position in our market.

Trade secrets and know-how can be difficult to protect. We require our employees to enter into written employment agreements containing provisions of confidentiality and obligations to assign to us any inventions generated in the course of their employment. We enter into written agreements that include confidentiality and intellectual property obligations to protect each party's property, potential trade secrets, proprietary know-how, and information. We further seek to protect our potential trade secrets, proprietary know-how, and information in part, by entering into non-disclosure and confidentiality agreements with parties who are given access to them, such as our corporate collaborators, outside scientific collaborators, CROs, CMOs, consultants, advisors and other third parties. With our consultants, contractors, and outside scientific collaborators, these agreements typically include invention assignment obligations. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us. 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 harmed.

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

We may be subject to claims that former employees, collaborators or other third parties have an interest in our patents or other intellectual property as an inventor or co-inventor. The failure to name the proper inventors on a patent application can result in the patents issuing thereon being unenforceable. Inventorship disputes may arise from conflicting views regarding the contributions of different individuals named as inventors, the effects of foreign laws where foreign nationals are involved in the development of the subject matter of the patent, conflicting obligations of third parties involved in developing our product candidates or as a result of questions regarding co-ownership of potential joint inventions. Litigation may be necessary to resolve these and other claims challenging inventorship and/or ownership. Alternatively, or additionally, we may enter into agreements to clarify the scope of our rights in such intellectual property. If we 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. Such an outcome could have a material adverse effect on our business. 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.

Our licensors may have relied on third-party consultants or collaborators or on funds from third parties, such as the U.S. government, such that our licensors are not the sole and exclusive owners of the patents we may in-license in the future. If other third parties have ownership rights or other rights to our in-licensed patents, they may be able to license such patents to our competitors, and our competitors could market competing products and technology. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

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

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 current or future trademarks or trade names may be challenged, infringed, circumvented or declared generic or descriptive or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. During trademark registration proceedings, we may receive rejections of our applications by the USPTO or in other foreign jurisdictions. Although we would be given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected. We may license our trademarks and tradenames to third parties, such as distributors. Although these license agreements may provide guidelines for how our trademarks and tradenames may be used, a breach of these agreements or misuse of our trademarks and tradenames by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names.

Moreover, any name we have proposed to use with our product candidate in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. Similar requirements exist in Europe. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA (or an equivalent administrative body in a foreign jurisdiction) objects to any of our proposed proprietary product names, it may be required to expend significant additional resources in an effort to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. Furthermore, in many countries, owning and maintaining a trademark registration may not provide an adequate defense against a subsequent infringement claim asserted by the owner of a senior trademark. 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. If we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

Risks Related to Our Common Stock

The stock price of our common stock may be volatile or may decline regardless of our operating performance and you may lose all or part of your investment.

The trading price of our common stock is likely to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume. In addition to the factors discussed in this “Risk Factors” section and elsewhere in this Annual Report on Form 10-K, these factors include:

- overall performance of the equity markets;
- our operating performance and the performance of other similar companies;
- the published opinions and third-party valuations by banking and market analysts;
- results from our ongoing clinical trials and future clinical trials with our current and future product candidates or of our competitors;
- adverse results or delays in clinical trials;
- failure to commercialize our product candidates;
- unanticipated serious safety concerns related to immuno-oncology or related to the use of our product candidates;
- changes in our projected operating results that we provide to the public, our failure to meet these projections or changes in recommendations by securities analys elect to follow our common stock;
- any delay in our regulatory filings for our product candidates and any adverse development or perceived adverse development with respect to the applicable reg authority’s review of such filings, including without limitation the FDA’s issuance of a “refusal to file” letter or a request for additional information;

- regulatory or legal developments in the United States and other countries;
- the level of expenses related to future product candidates or clinical development programs;

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- our failure to achieve product development goals in the timeframe we announce;
- announcements of acquisitions, strategic alliances or significant agreements by us or by our competitors;
- recruitment or departure of key personnel;
- the economy as a whole and market conditions in our industry;
- trading activity by a limited number of stockholders who together beneficially own a majority of our outstanding common stock;
- the expiration of market standoff or contractual lock-up agreements;
- the size of our public float;
- political uncertainty and/or instability in the United States;
- States and throughout the ongoing and future impact of the COVID-19 pandemic and actions taken to slow its spread; world; and
- any other factors discussed in this Annual Report on Form 10-K.

In addition, the stock markets have experienced extreme price and volume fluctuations that have affected and continue to affect the market prices of equity securities of many immuno-oncology companies. Stock prices of many immuno-oncology companies have fluctuated in a manner unrelated or disproportionate to the operating performance of those companies. The trading prices for common stock of other biopharmaceutical companies have also been highly volatile as a result of the COVID-19 pandemic. high inflation environment and geopolitical conflict in Ukraine and the Middle East. In the past, stockholders have filed securities class action litigation following periods of market volatility. If we were to become involved in securities litigation, it could subject us to substantial costs, divert resources and the attention of management from our business and adversely affect our business.

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Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

As of December 31, 2022 December 31, 2023, our executive officers, directors, 5% stockholders and their affiliates beneficially owned approximately 81.7% 93.7% of our voting stock. Therefore, these stockholders will have the ability to influence us through their ownership positions. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders, acting together, may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may believe are in your best interest as one of our stockholders.

If there are substantial sales of shares of our common stock, the price of our common stock could decline.

The price of our common stock could decline if there are substantial sales of our common stock, particularly sales by our directors, executive officers and significant stockholders, or if there is a large number of shares of our common stock available for sale and the market perceives that sales will occur. As of December 31, 2022 December 31, 2023, we had 28,815,267 65,880,914 shares of common stock outstanding. Substantially all of our outstanding shares of common stock are currently able to be sold freely in the public market, subject to certain restrictions that may apply to shares of our common stock held by our affiliates. affiliates and by certain participants in our August 2023 private placement. The market price of our common stock could decline as a result of the sale of a substantial number of shares of our common stock in the public market or the perception in the market that the holders of a large number of shares intend to sell their shares.

Delaware law and provisions in our amended and restated certificate of incorporation and bylaws could make a merger, tender offer or proxy contest difficult, thereby depressing the trading price of our common stock.

Our amended and restated certificate of incorporation and bylaws contain provisions that could depress the trading price of our common stock by acting to discourage, delay or prevent a change of control of our company or changes in our management that the stockholders of our company may deem advantageous. These provisions include: provisions:

- establish a classified board of directors so that not all members of our board of directors are elected at one time;
- permit the board of directors to establish the number of directors and fill any vacancies and newly-created directorships;
- provide that directors may only be removed for cause and only by the affirmative vote of the holders of at least a majority of the voting power of all then outstanding of our capital stock;

- require super-majority voting to amend some provisions in our amended and restated certificate of incorporation and bylaws;
- authorize the issuance of “blank check” preferred stock that our board of directors could use to implement a stockholder rights plan;
- prohibit stockholders from calling special meetings of stockholders;
- prohibit stockholder action by written consent, which requires all stockholder actions to be taken at a meeting of our stockholders;
- provide that the board of directors is expressly authorized to make, alter or repeal our bylaws;
- restrict the forum for certain litigation against us to Delaware; and
- establish advance notice requirements for nominations for election to our board of directors or for proposing matters that can be acted upon by stockholders at stockholder meetings.

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

Our amended and restated certificate of incorporation designates a state or federal court located within the state of Delaware as the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders’ ability to choose the judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, to the fullest extent permitted by law, the sole and exclusive forum for (1) any derivative action or proceeding brought on our behalf under Delaware law; (2) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders; (3) any action arising pursuant to any provision of the Delaware General Corporation Law (DGCL), our amended and restated certificate of incorporation or bylaws; (4) any other action asserting a claim that is governed by the internal affairs doctrine; or (5) any other action asserting an “internal corporate claim,” as defined in Section 115 of the DGCL, shall be the Court of Chancery of the State of Delaware (or, if the Court of Chancery does not have jurisdiction, the federal district court for the District of Delaware) in all cases subject to the court having jurisdiction over indispensable parties named as defendants. These exclusive-forum provisions do not apply to claims under the Securities Act or the Securities Exchange Act of 1934, as amended (the Exchange Act).

To the extent that any such claims may be based upon federal law claims, Section 27 of the Exchange Act creates exclusive federal jurisdiction over all suits brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder.

Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. However, our amended and restated certificate of incorporation contains a federal forum provision which provides that unless the company Company consents in writing to the selection of an alternative forum, the federal district courts of the United States of America will be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act.

Any person or entity purchasing or otherwise acquiring any interest in any of our securities shall be deemed to have notice of and consented to this provision. This exclusive forum provision may limit a stockholder’s ability to bring a claim in a judicial forum of its choosing for disputes with us or our directors, officers or other employees, which may discourage lawsuits against us and our directors, officers and other employees. If a court were to find the exclusive forum provision in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving the dispute in other jurisdictions, which could harm our results of operations.

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

Additional capital will be needed in the future to continue our planned operations. To the extent we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. We may sell common stock, convertible securities or other equity securities 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 in more than one transaction, investors may

be materially diluted by subsequent sales. These sales may also result in material dilution to our existing stockholders, and new investors could gain rights superior to our existing stockholders.

Pursuant to our the IO Biotech, Inc. 2021 Equity Incentive Plan (the 2021 Equity Plan), our management is we are authorized to grant stock options and other equity-based awards to our employees, directors and consultants, which consultants. In addition, pursuant to the IO Biotech, Inc. 2023 Inducement Award Plan (2023 Inducement Plan), we are eligible to grant stock options and other equity-based awards to employees as an inducement for them to join us. Equity-based awards granted under the 2021 Equity Plan and the 2023 Inducement Plan would also cause dilution to our stockholders. The number of shares of our common stock reserved for issuance under our the 2021 Equity Plan will automatically increase on January 1 of each calendar year, starting on January 1, 2022 through January 1, 2031, by an amount equal to the lesser of (1) 4% of the total number of shares of our common stock outstanding on the last day of the calendar month before the date of each automatic increase; or (2) a lesser number of shares determined by our board of directors prior to the applicable January 1st. If our board of directors elects to increase the number of shares available for future grant by the maximum amount each year, our stockholders may experience additional dilution, which could cause our stock price to fall. The maximum number of shares reserved for issuance under the 2023 Inducement Plan is 1,976,427 shares.

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

We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to stockholders will therefore be limited to the appreciation of their stock.

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

We are an "emerging growth company" as defined in the Jumpstart Our Business Startups Act (the JOBS Act), and we intend to take advantage of some of the exemptions from reporting requirements that are applicable to other public companies that are not emerging growth companies, including:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly re "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure;
- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotatic supplement to the auditor's report providing additional information about the audit and the financial statements;
- reduced disclosure obligations regarding executive compensation; and
- not being required to hold a non-binding advisory vote on executive compensation or obtain stockholder approval of any golden parachute payments not pre approved.

In addition, as an "emerging growth company" the JOBS Act allows us to delay adoption of new or revised accounting pronouncements applicable to public companies until such pronouncements are made applicable to private companies, unless we later irrevocably elect not to avail ourselves of this exemption. We have elected to use this extended transition period under the JOBS Act. As a result, our financial statements may not be comparable to the financial statements of issuers who are required to comply with the effective dates for new or revised accounting standards that are applicable to public companies, which may make comparison of our financials to those of other public companies more difficult. We will remain an emerging growth company until the earliest of (1) the end of the fiscal year following the fifth anniversary of our initial public offering; (2) the last day of the fiscal year during which our annual gross revenues are $1.235 billion or more; (3) the date on which we have, during the previous three-year period, issued more than $1.0 billion in non-convertible debt securities; and (4) the end of any fiscal year in which the market value of our common stock held by non-affiliates exceeded $700.0 million as of the end of the second quarter of that fiscal year.

We are also a "smaller reporting company meaning that the market value of our stock held by non-affiliates is less than $700 million and our annual revenue was less than $100 million during the most recently completed fiscal year. Smaller reporting companies may take advantage of certain reduced disclosure obligations, including, among other things, providing only two years of audited financial statements in our Annual Report on Form 10-K, and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation. To the extent we take advantage of such reduced disclosure obligations, it may also make comparison of our financial statements with other public companies difficult or impossible. We will remain a smaller reporting company until the last day of the fiscal year in which (i)

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the market value of our common stock held by non-affiliates exceeds $250 million as of the end of that year's second fiscal quarter and our annual revenues exceeds $100 million during such completed fiscal year, or (ii) the market value of our common stock held by non-affiliates exceeds $700 million, regardless of our annual revenue, as of the end of that year's second fiscal quarter.

Investors may find our common stock less attractive to the extent we will rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

General Risk Factors

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

As a public company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. In addition, the Sarbanes-Oxley Act of 2002, as amended (the Sarbanes-Oxley Act), as well as rules subsequently implemented by the SEC and Nasdaq, have imposed various requirements on public companies. In July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act (the Dodd-Frank Act) was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas such as "say "Say on pay" Pay" and proxy access. Recent legislation permits smaller "emerging growth companies" to implement many of these requirements over a longer period and up to five years from the pricing of our IPO. We intend to take have taken advantage of this new legislation but cannot guarantee that we will not be required to implement these requirements sooner than budgeted or planned and thereby incur unexpected expenses. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costlier. costlier than when we were a private company. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain our current levels of such coverage.insurance.

Failure to build our finance infrastructure and improve our accounting systems and controls could impair our ability to comply with the financial reporting and internal controls requirements for publicly traded companies.

As a public company, we operate in an increasingly demanding regulatory environment, which requires us to comply with the Sarbanes-Oxley Act, the regulations of Nasdaq, the rules and regulations of the SEC, expanded disclosure requirements, accelerated reporting requirements and more complex accounting rules. Company responsibilities required by the Sarbanes-Oxley Act include establishing corporate oversight and adequate internal control over financial reporting and disclosure controls and procedures. Effective internal controls are necessary for us to produce reliable financial reports and are important to help prevent financial fraud. Commencing with our fiscal year ending December 31, 2022, we must perform system and process evaluation and testing of our internal controls over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting in our Form 10-K filing for that and each subsequent year, as required by Section 404 of the Sarbanes-Oxley Act. Prior to our IPO, we were not required to test our internal controls within a specified period and, as a result, we may experience difficulty in meeting these reporting requirements. For example, in connection with the audit of our financial statements for the years ended December 31, 2021 and 2020, we and our independent registered public accounting firm identified a material weakness in our internal control over financial reporting. This material weakness was not previously remediated, and in connection with the preparation of our consolidated financial statements for the year ended December 31, 2021, the Company identified an error, which resulted in a restatement as disclosed in our Current Report on Form 8-K filed on December 17, 2021. For the year ended December 31, 2022, this material weakness has been was remediated and no additional material weaknesses were identified for the year ended December 31, 2023, but we could experience further difficulty with internal control over financing reporting in the future.

Our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, or if we are unable to maintain proper and effective internal controls, we may not be able to produce timely and accurate financial statements. If we cannot provide reliable financial reports or prevent fraud, our business and results of operations could be

harmed, investors could lose confidence in our reported financial information and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities.

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

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

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. These limitations led to an error that the Company identified in connection with the preparation of our consolidated financial statements, which resulted in a restatement as disclosed in our Current Report on Form 8-K filed on December 17, 2021. For example, our directors or executive officers could inadvertently fail to disclose a new relationship or arrangement causing us to fail to make any related party transaction disclosures. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

Future changes in financial accounting standards or practices may cause adverse and unexpected revenue fluctuations and adversely affect our reported results of operations.

Future changes in financial accounting standards may cause adverse, unexpected revenue fluctuations and affect our reported financial position or results of operations. Financial accounting standards in the United States are constantly under review and new pronouncements and varying interpretations of pronouncements have occurred with frequency in the past and are expected to occur again in the future. As a result, we may be required to make changes in our accounting policies. Those changes could affect our financial condition and results of operations or the way in which such financial condition and results of operations are reported. We intend to invest resources to comply with evolving standards, and this investment may result in increased general and administrative expenses and a diversion of management time and attention from business activities to compliance activities. See the section titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Recent Accounting Pronouncements.”

Changes in tax laws or regulations that are applied adversely to us or our customers may have a material adverse effect on our business, cash flow, financial condition or results of operations.

New income, sales, use, or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could adversely affect our business operations and financial performance. Further, existing tax laws, statutes, rules, regulations, or ordinances could be interpreted, changed, modified, or applied adversely to us. For example, the TCJA enacted many significant changes to the U.S. tax laws. Future guidance from the IRS and other tax authorities with respect to the TCJA may affect us, and certain aspects of the TCJA could be repealed or modified in future legislation. For example, the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) modified certain provisions of the TCJA. In addition, it is uncertain if and to what extent various states will conform to the TCJA or any newly enacted federal tax legislation. For example, the U.S. government recently enacted the IRA which, among other things, significantly changes the taxation of certain business entities, including by imposing a 1% excise tax on certain share buybacks, effective for tax years beginning in 2023. If and when applicable, it is possible that the 1% excise tax on share buybacks could result in an additional tax liability over the regular federal corporate tax liability in a given year. Any resulting tax liability could adverse impact our business, financial condition, results of operation, and liquidity. Changes in corporate tax rates, the realization of net deferred tax assets relating to our operations, the taxation of foreign earnings, and the deductibility of expenses under the TCJA or future reform legislation could have a material impact on the value of our deferred tax assets, could result in significant one-time one time charges, and could increase our future U.S. tax expense.

In addition, the recent and upcoming presidential and congressional elections in the United States could also result in significant changes in, and uncertainty with respect to, tax legislation, regulation and government policy directly affecting us and our business. For example, the United States government may enact significant changes to the taxation of business entities including, among others, a permanent increase in the corporate income tax rate, an increase in the tax rate applicable to the global intangible low-taxed income and elimination of certain exemptions, and the imposition of minimum taxes or surtaxes on certain types of income. The likelihood of these changes being enacted or implemented is unclear.

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Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and stock price.

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The global credit and financial markets have recently experienced extreme volatility and disruptions, including as a result of recent developments in the U.S. banking sector as well as and geopolitical conflict in Ukraine and the consequences of the COVID-19 pandemic, Middle East, leading to increased inflation, diminished liquidity and credit

availability, declines in consumer confidence, declines in economic growth, and uncertainty about economic and bank-system stability. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, volatile business environment or continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay or abandon clinical development plans. In addition, there is a risk that one or more of our current service providers, manufacturers and other partners may not survive an economic downturn, which could directly affect our ability to attain our drug-candidate-development goals on schedule and on budget.

We will have broad discretion in the use of our existing cash and cash equivalents and may not use them effectively or in ways that increase the value of our share price.

We cannot specify with any certainty the particular uses of our existing cash and cash equivalents. We will have broad discretion in the application of our existing cash and cash equivalents, including working capital and other general corporate purposes, and you and other stockholders may disagree with how we spend or invest our cash and cash equivalents. The failure by our management to apply these funds effectively could adversely affect our business and financial condition. Pending their use, we may invest our cash and cash equivalents in a manner that does not produce income or that loses value. These investments may not yield a favorable return to our investors.

Our internal information technology systems, or those of our third-party CROs or other contractors or consultants, may fail or suffer security breaches, loss or leakage of data, and other disruptions, which could result in a material disruption of our product candidates' development programs, compromise sensitive information related to our business or prevent us from accessing critical information, potentially exposing us to liability or otherwise adversely affecting our business.

We are increasingly dependent upon information technology systems, infrastructure and data to operate our business. In the ordinary course of business, we collect, store and transmit confidential information (including but not limited to intellectual property, proprietary business information and personal information). It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information. We have also outsourced elements of our operations to third parties, and as a result we manage a number of third-party contractors who have access to our confidential information.

Despite the implementation of security measures, given their size and complexity and the increasing amounts of confidential information that they maintain, our internal information technology systems and those of our third-party CROs and other contractors and consultants are potentially vulnerable to breakdown or other damage or interruption from service interruptions, system malfunction, natural disasters, terrorism, war and telecommunication and electrical failures, as well as security breaches from inadvertent or intentional actions by our employees, contractors, consultants, business partners, and/or other third parties, or from cyber-attacks by malicious third parties (including the deployment of harmful malware, ransomware, extortion, account takeover attacks, degradation of service attacks, denial-of-service attacks, "phishing," or social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information), which may compromise our system infrastructure or lead to data leakage. We have technology security initiatives and disaster recovery plans in place to mitigate our risk to these vulnerabilities, but these measures may not be adequately designed or implemented to ensure that our operations are not disrupted or that data security breaches do not occur. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and reputational damage.

Hackers and data thieves are increasingly sophisticated and operate large-scale and complex automated attacks which may remain undetected until after they occur. We cannot assure you that our data protection efforts and our investment in information technology will prevent significant breakdowns, data leakages, breaches in our systems or other cyber incidents that could have a material adverse effect upon our reputation, business, operations or financial condition. For example, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our programs and the development of our product candidates could be delayed. In addition, the loss of clinical trial data for our product candidates could result in delays in our marketing approval efforts and significantly increase our costs to recover or reproduce the data. Furthermore, significant disruptions of our internal information technology systems or security breaches could result in the

loss, misappropriation, and/or unauthorized access, use, or disclosure of, or the prevention of access to, confidential information (including trade secrets or other intellectual property, proprietary business information, and personal information), which could result in financial, legal, business, and reputational harm to us. Like all businesses we may be increasingly subject to ransomware or other malware that could significantly disrupt our business operations, or disable or interfere with necessary access to essential data or processes. Numerous recent attacks of this nature have also involved exfiltration and disclosure of sensitive or confidential personal or proprietary information, or intellectual property, when victim companies have not paid the cyber criminals substantial ransom payments. For example, any such event that leads to unauthorized access, use, disclosure, unavailability, or compromised integrity of personal or other sensitive or essential information, including personal information regarding our clinical trial subjects or employees, could harm our reputation directly, compel us to comply with federal and/or state breach notification laws and foreign law equivalents, subject us to mandatory corrective action, increase

the costs we incur to protect against such information security breaches, such as increased investment in technology, render key personnel unable to perform duties or communicate throughout the organization and otherwise subject us to fines and other liability under laws and regulations that protect the privacy and security of personal information, which could result in significant legal and financial exposure and reputational damages that could potentially have an adverse effect on our business.

The costs of mitigating cybersecurity risks are significant and are likely to increase in the future. These costs include, but are not limited to, retaining the services of cybersecurity providers; compliance costs arising out of existing and future cybersecurity, data protection and privacy laws and regulations; and costs related to maintaining redundant networks, data backups and other damage-mitigation measures. We also cannot be certain that our existing insurance coverage will continue to be available on acceptable terms or in amounts sufficient to cover the potentially significant losses that may result from a security incident or breach or that the insurer will not deny coverage of any future claim.

Our operations as a global company subject us to various risks, and our failure to manage these risks could adversely affect our business, results of operations, cash flows, financial condition and/or prospects.

We face significant operational risks as a result of doing business globally, such as:

- fluctuations in currency exchange rates (in particular, between U.S. dollars, Euros and Danish Kroner);
- potentially adverse tax consequences, including the complexities of foreign value-added tax systems, tax inefficiencies related to our corporate structure, and po restrictions on the repatriation of earnings;
- export restrictions, trade regulations and foreign tax laws;
- customs clearance and shipping delays;
- the burdens of complying with a wide variety of foreign laws and different legal standards; and
- increased financial accounting and reporting burdens and complexities.

If one or more of these risks are realized, it could have a material adverse effect on our business, results of operations, cash flows, financial condition and/or prospect.

Global economic and political instability and conflicts, such as the conflict between in Russia and Ukraine and conflicts in the Middle East, could adversely affect our business, financial condition or results of operations.

Our business could be adversely affected by unstable economic and political conditions within the United States and foreign jurisdictions and geopolitical conflicts, such as the conflict between Russia in Ukraine and Ukraine. conflicts in the Middle East. While we do not have any operations in either country Russia or Ukraine at this time, the current military conflict, and related sanctions, as well as export controls or actions that may be initiated by nations and regions including the United States, the European Union EU or Russia (e.g., potential cyberattacks, disruption of energy flows, disruptions to supply chains, etc.) and other potential uncertainties could adversely affect our business. Certain of our clinical trial sites are located in Israel and conflicts in the Middle East may delay, limit or hinder ongoing, planned or future trials and affect enrollment and retention of patients. Inability to enroll or retain patients and limitations or delays in clinical trials could increase costs and cause setbacks in product development. In the event geopolitical tensions fail to abate or deteriorate further, additional governmental sanctions may be enacted adversely impacting the global economy, which could adversely affect our business, financial condition or results of operations.

We or the third parties upon whom we depend may be adversely affected by earthquakes, fires or other natural disasters and/or terrorism and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

If earthquakes, fires, other natural disasters, terrorism and similar unforeseen events beyond our control prevent us from using all or a significant portion of our headquarters or other facilities, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. We do not have a disaster recovery or business continuity plan in place and may incur substantial expenses as a result of the absence or limited nature of our internal or third-party service provider

disaster recovery and business continuity plans, which could have a material adverse effect on our business. In addition, the long-term effects of climate change on general economic conditions and the pharmaceutical manufacturing and distribution industry in particular are unclear, and changes in the supply, demand or available sources of energy and the regulatory and other costs associated with energy production and delivery may affect the availability or cost of goods and services, including raw materials and other natural resources, necessary to run our business. Furthermore, certain parties in our supply chain are operating from single sites, increasing their vulnerability to natural disasters or other sudden, unforeseen and severe adverse events. If such an event were to affect our supply chain, it could have a material adverse effect on our ability to conduct our clinical trials, our development plans and business.

We are subject to certain U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations. We can face serious consequences for violations.any violations of such laws.

U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations (collectively, Trade Laws) prohibit, among other things, companies and their employees, agents, CROs, legal counsel, accountants, consultants, contractors, and other partners from authorizing, promising, offering, providing, soliciting, or receiving directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. Violations of Trade Laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. We also expect to continue our non-U.S. activities, which may increase over time. We expect to rely on third parties for research, preclinical studies, and clinical trials and/or to obtain necessary permits, licenses, patent registrations, and other marketing approvals. We can be held liable for the corrupt or other illegal activities of our personnel, agents, or partners, even if we do not explicitly authorize or have prior knowledge of such activities.

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

We, and the third parties with whom we share our facilities, are subject to numerous 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. Each of our operations involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. Each of our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. We could be held liable for any resulting damages in the event of contamination or injury resulting from the use of hazardous materials by us or the third parties with whom we share our facilities, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

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

In addition, 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 and development. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

We could be subject to securities class action litigation.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because pharmaceutical companies have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

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

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. Securities and industry analysts do not currently, and may never, publish research on our company. If no or only very few securities analysts commence coverage of us, or if industry analysts cease coverage of us, the trading price for our common stock could be negatively affected. If one or more of the analysts who cover us downgrade

our common stock or publish inaccurate or unfavorable research about our business, our common stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, demand for our common stock could decrease, which might cause our common stock price and trading volume to decline.

Failure to meet investor and stakeholder expectations regarding environmental, social and corporate governance, or "ESG" matters may damage our reputation.

There is an increasing focus from certain investors, employees and other stakeholders concerning ESG matters. Additionally, public interest and legislative pressure related to public companies' ESG practices continue to grow. If our ESG practices fail to meet investor, employee or other stakeholders' evolving expectations and standards for responsible corporate citizenship in areas including environmental stewardship, Board of Directors and employee diversity, human capital management, corporate governance and

transparency, our reputation, brand, appeal to investors and employee retention may be negatively impacted, which could have a material adverse effect on our business or financial condition.

Item 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity Risk Management, Strategy and Governance

Risk Management and Strategy

We regularly assess risks from cybersecurity threats, monitor our information systems for potential vulnerabilities, and test those systems pursuant to our information and cybersecurity policies, processes, and practices. We maintain a Cybersecurity Incident Response Plan that establishes an incident response team led by our Head of Information Technology and describes our response protocol for cybersecurity incidents. To help 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. Assessment of cybersecurity threats is included as part of our overall risk management processes.

We have engaged consultants and other third parties to assist in our assessment of risks from cybersecurity threats and to evaluate our cybersecurity prevention and response systems and processes. At times, we may engage third parties to assist in the management and mitigation of a particular threat.

We are requiring each of our significant third-party service providers to agree that it will implement and maintain appropriate security measures that are consistent with applicable law, implement and maintain reasonable security measures in connection with their work with us, and promptly report any suspected breach of its security measures that may affect our company.

Governance

Our board of directors, as a whole and through the Audit Committee, is responsible for the oversight of risk management, including oversight of risks from cybersecurity threats, and discusses with management our major risk exposures, including from cybersecurity threats, their potential impact on us, and the steps we take to manage them.

Our Head of Information Technology, reporting to our Chief Financial Officer, has day-to-day responsibility for preventing, detecting, mitigating and remediating cybersecurity risks. The individual currently serving in this role has over twenty years of experience in information technology and cybersecurity. Our Head of Information Technology leads an incident response team that includes members of executive management, including members of our legal team, and is charged with assessing and managing material cybersecurity risks, and with notifying our executive management committee and disclosure committee of potential material cybersecurity incidents. Executive management provides updates on our cybersecurity risk profile to our Audit Committee on at least a quarterly basis.

Cybersecurity Threats

As of the date of this report, we have not identified cybersecurity threats, including as a result of any previous cybersecurity incidents, that have materially affected us, including our business strategy, results of operations or financial condition. We and our third-party service providers have, however, been the target of cybersecurity threats and we expect these threats to continue. For additional information regarding risks from cybersecurity threats, please refer to Item 1A, “Risk Factors,” in this annual report on Form 10-K.

Item 1D. Section 16 Officers and Directors Rule 10b5-1 Plan.

None.

Item 2. Properties.

We lease a facility containing approximately 622 square meters of office space for our main office, which is located at COBIS, Ole Maaloes Maaløes Vej 3, 2200 DK-2200 Copenhagen N, Denmark. The lease expires on December 31, 2027. in December 2027. We also lease lab space at COBIS, Ole Maaloes Maaløes Vej 3, 2200 DK-2200 Copenhagen N, Denmark. The initial lease expires on December 31, 2022 and a new lease commences on January 1, 2023, which expires on December 31, 2027. in December 2027.

In the United States, we lease facilities office space in New York, for office space, located at 430 East 29th Street, New York, New York, and a facility lab space in Maryland, for lab space, located at 5640 Fishers Lane, Suite C, Rockville, Maryland. The New York lease expires on February 28, 2027 in January 2027 and the Maryland lease expires on March 31, 2027. in May 2027.

For our UK team, we lease an office facility space located at 18 Maryport Street, Monmouthshire, No 1 Langstone Business Park, Newport, UK. This The lease can be terminated at our convenience.expires in May 2025.

We believe that our current facilities are adequate for our current needs and that suitable additional or substitute space at commercially reasonable terms will be available as needed to accommodate any future expansion of our operations.

Item 3. Legal Proceedings.

From time to time, we may be a party to litigation or subject to claims incidental to the ordinary course of business. Although the results of litigation and claims cannot be predicted with certainty, we currently believe that the final outcome of these ordinary course matters will not have a material adverse effect on our business. Regardless of the outcomes, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors. We are not currently a party to any material legal proceedings.

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 for Common Stock

Our common stock is listed on the Nasdaq Global Select Market under the symbol "IOBT."

Dividend Policy

We have never declared or paid any dividends on our common stock. We anticipate that we will retain all of our future earnings, if any, for use in the operation and expansion of our business and do not anticipate paying cash dividends in the foreseeable future.

Stockholders

As of March 9, 2023 February 26, 2024, we had 28,815,267 65,880,914 shares of common stock outstanding held by 12 13 holders of record. The actual number of stockholders is greater than this number of record holders and includes stockholders who are beneficial owners but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Equity Compensation Plans

The following table details information regarding our existing equity compensation as of December 31, 2022 December 31, 2023:

Plan Category	Securities to be Issued Upon Exercise of Outstanding Options and Warrants (in thousands) (a)	Weighted Average Exercise Price of Outstanding Options and Warrants (b)	Number of Securities Remaining Available for Issuance Under Equity Compensation Plans (Excluding Securities reflected in Column (a)) (c)	Securities to be Issued Upon Exercise of Outstanding Options and Warrants (in thousands) (a)	Weighted Average Exercise Price of Outstanding Options and Warrants (b)	Number of Securities Remaining Available for Issuance Under Equity Compensation Plans (Excluding Securities reflected in Column (a)) (in thousands) (c)

Equity compensation plans approved by security holders	3,920	$ 10.77	1,389	5,504	$ 7.53	593
Equity compensation plans not approved by security holders				348	$ 1.86	1,976
Total	3,920	$ 10.77	1,389	5,852	$ 7.20	2,570

See "Item "Item 8. Financial Statements and Supplementary Data - Notes to the Consolidated Financial Statements - Note 12. 11. Equity-Based Compensation" Compensation" for additional information on compensation plans under which equity securities of the registrant are authorized for issuance.

Use of Proceeds

Recent Sales of Unregistered Securities

On August 9, 2023, we completed a private placement transaction (the Private Placement) in which we issued and sold (i) an aggregate of 37,065,647 shares of the Company's common stock, $0.001 par value (the Common Stock), and (ii) 37,065,647 warrants to purchase up to 37,065,647 shares of Common Stock, $0.001 par value, to the Purchasers (the Warrants). The offer and sale of securities in the Private Placement were exempt from registration under Section 4(a)(2) of the Securities Act as transactions by an issuer not involving a public offering. The Purchasers acquired the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the securities issued in the Private Placement. Each of the Purchasers was an accredited person and had adequate access to information about the Company. The co-placement agents in connection with the Private Placement were Morgan Stanley & Co. LLC & Piper Sandler & Co.

We raised $71.9 million in net proceeds from the Private Placement after deducting underwriting discounts, commissions and other issuance costs of $3.2 million. No underwriting discounts and commissions or offering expenses were paid directly or indirectly to any of our directors of officers (or their associates) or persons owning ten percent or more of any class of our equity securities or to any other affiliates.

Use of Proceeds From Registered Securities

On November 9, 2021, we completed our IPO in which we issued and sold 8,222,500 shares of common stock, $0.001 par value per share, including 1,072,500 shares of common stock sold pursuant to the underwriters' exercise of their option to purchase additional shares of common stock. The offer and sale of the shares in the IPO was registered under the Securities Act pursuant to a registration statements statement on Form S-1 (File No. 333-260301), which was filed with the SEC on October 15, 2021 and subsequently amended and declared effective on November 4, 2021, and the prospectus included therein or the Prospectus. (the Prospectus). The underwriters of the IPO were Modrgan Morgan Stanley & Co. LLC, Jefferies LLC, Cowen and Company, LLC and Kempen & Co USA, U.S.A, Inc.

We raised approximately $103.3 million in net proceeds from the IPO after deducting underwriting discounts and commissions of $8.0 million and other offering expenses of approximately $3.8 million payable by us. No underwriting discounts and commissions or offering expenses were paid directly or indirectly to any of our directors of officers (or their associates) or persons owning ten percent or more of any class of our equity securities or to any other affiliates.

There has been no material change in the planned use of proceeds from our IPO, as described in the Prospectus.

Purchases of Equity Securities by the Issuer and Affiliated Parties

None.

Item 6. [Reserved].

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

You should read the following discussion and analysis of our financial condition and results of operations in conjunction with the consolidated financial statements and the related notes to those statements included later in this Annual Report. In addition to historical financial information, the following discussion contains forward-looking statements that reflect our plans, estimates, beliefs and expectations that involve risks and uncertainties. Our actual results and the timing of events could differ materially from those discussed in these 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," and "Special Note Regarding Forward-Looking Statements."

Overview

We are a clinical-stage biopharmaceutical company developing novel, immune-modulating therapeutic cancer vaccines based on our T-win technology T-win® platform. Our T-win product candidates are designed to induce kill both tumor cells and immune-suppressive cells in the immune system to simultaneously TME by stimulating the activation and expansion of T cells against IDO+ and/or PD-L1+ target positive cells, resulting in the modulation of the TME, creating a more pro-inflammatory environment, and disrupt multiple pathways that regulate tumor-induced immunosuppression. the potentiation of anti-tumor activity by unleashing the tumor killing by effector T cells. We believe this represents could represent a paradigm shift in the management of cancer and that our product candidates have the potential to become cornerstones advance the oncology treatment paradigm, amplifying treatment effects across the spectrum of the treatment regimens of multiple solid tumors. melanoma and other tumor types. Our lead product therapeutic cancer vaccine candidate, IO102-IO103, is designed to target the immunosuppressive mechanisms mediated by key immunosuppressive proteins such as Indoleamine 2,3-dioxygenase (IDO) IDO and programmed death ligand (PD-L1). PD-L1. In a single-arm Phase 1/2 clinical trial of 30 patients with metastatic melanoma, with the primary objective of investigating safety and tolerability, the secondary objective of investigating immunogenicity, and the tertiary objective of investigating clinical efficacy, IO102-IO103 in combination with nivolumab, an anti-PD-1 checkpoint inhibitor, demonstrated proof of concept by increasing the ORR of what is reported with an ability to induce anti-PD-1 antibody alone. The combination induced meaningful tumor regression and establish achieved rapid, deep and durable antitumor response while achieving responses with a manageable favorable tolerability profile for patients. without adding systemic toxicity to what is seen with an anti-PD-1 monotherapy in this patient population. Safety was the primary endpoint of this trial, immune response was the secondary endpoint and clinical efficacy was the tertiary endpoint. The clinical efficacy endpoints in this trial included OR, PFS and OS. In this trial, we observed a confirmed overall response rate ORR of 73% and as per RECIST 1.1, a complete response rate CRR of 50%. and 25.5 months of PFS. Based on the these results, from this trial, IO102-IO103, in combination with pembrolizumab, was granted BTD by the FDA for treatment of unresectable/metastatic melanoma.melanoma and we initiated a global Phase 3 trial.

We enrolled the first patient in a potentially registrational Phase 3 trial for IO102-IO103 in combination with pembrolizumab as a potential first-line treatment in advanced melanoma, the IOB-013/KN-D18 trial, in May of 2022. We have made significant progress with randomized 225 patients in June 2023 and fully enrolled the activation trial in November 2023. On June 14, 2023, we announced that we amended the protocol and increased the number of clinical sites participating patients to be enrolled in the Phase 3 IOB-013/KN-D18 trial ending February 2023 with nearly 100 active sites in the trial, compared to 55 at the end of October 2022. The IOB-013/KN-D18 trial has a target enrollment of from original 300 patients and is designed with an interim analysis of ORR one year after 75% of to revised 380 patients, have been randomized and a final analysis of which could potentially accelerate the time to reach the primary endpoint of PFS, for the full trial population. We expect to enroll 75% of patients which is an event-based driven analysis and will be assessed when 226 events (progression or death) are registered in the trial. The primary endpoint is powered at 89% to detect a hazard ratio of 0.65. The Phase 3 trial by mid-2023 and protocol has a planned interim analysis of ORR to complete recruitment by be conducted 12 months after 225 patients have been randomized; if the end investigational arm demonstrates a highly statistically significant improvement in ORR compared to the control arm, with a p-value<0.005, then the interim analysis could allow for potential submission of 2023. a BLA for accelerated approval in the United States. When we designed the interim analysis, we assumed that patients treated with IO102-IO103 in combination with pembrolizumab would show an ~18-point improvement in ORR compared to the patients treated with pembrolizumab alone. The trial design and discussions with FDA are aimed at potentially pursuing accelerated approval, if the trial data are favorable, based on the interim analysis of ORR, supported by other data. If the data are supportive, we also plan to file a MAA with the EMA based on the primary endpoint of PFS. PFS after the data are available, which is expected to occur in the second half of 2025.

Our ability to generate revenue from product sales sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of one or more of our product candidates. Our operations to date have been financed primarily by aggregate net proceeds of $288.7 million $360.6 million from the issuance of convertible preference shares, convertible notes, ordinary shares, our IPO and most recently, our IPO. Private Placement. On November 9, 2021 August 9, 2023, we completed an IPO of our common stock and issued and sold 8,222,500 shares of common stock at a public offering price of $14.00 per share, including 1,072,500 shares of common stock sold the Private Placement, pursuant to the underwriters' exercise of their option to purchase additional shares of common stock, resulting which we raised $71.9 million in net proceeds of $103.3 million after deducting underwriting discounts and commissions and estimated offering expenses. expenses of $3.2 million. Since inception, we have had significant operating losses. Our net loss was $71.5 million $86.1 million and $67.9 million $71.5 million for the years ended December 31, 2022 December 31, 2023 and 2021, 2022,

respectively. As of December 31, 2022 December 31, 2023, we had an accumulated deficit of $177.7 million $263.8 million and $142.6 million $143.2 million in cash and cash equivalents.

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Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our accounts payable and accrued expenses. We expect to continue to incur net losses for the foreseeable future, and we expect our to continue to incur significant research and development expenses and general and administrative expenses, and capital expenditures will continue to increase. expenses. In particular, we expect our expenses to increase as we continue our development of, and seek regulatory approvals for, our product candidates, as well as hire additional personnel, pay fees to outside consultants, lawyers and accountants, and incur other increased costs associated with being a public company. In addition, if and when we seek and obtain regulatory approval to commercialize any product candidate, we will also incur increased expenses in connection with commercialization and marketing of any such product. Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of our clinical trials and our expenditures on other research and development activities.

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Based upon our current operating plan, we believe that our existing cash and cash equivalents of $142.6 million $143.2 million as of December 31, 2022 December 31, 2023, will be sufficient to continue funding our development activities through into the third fourth quarter of 2024. 2025. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. To finance our operations beyond that point we will need to raise additional capital, which, though we were successful in raising additional capital through the Private Placement, cannot be assured.assured and which we may not be able to pursue successfully again in the future.

To date, we have not had any products approved for sale and, therefore, have not generated any product revenue. We do not expect to generate any revenues from product sales unless and until we successfully complete development and obtain regulatory approval for one or more of our product candidates. If we obtain regulatory approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. distribution, and associated regulatory and compliance costs. As a result, until such time, if ever, that we can generate substantial product revenue, we expect to finance our cash needs through equity offerings, debt financings or other capital sources, including collaborations, licenses or similar arrangements. However, we may be unable to raise additional funds or enter into such other arrangements when needed or on favorable terms, if at all. Any failure to raise capital as and when needed could have a negative impact on our financial condition and on our ability to pursue our business plans and strategies, including our research and development activities. If we are unable to raise capital, we will need to delay, reduce or terminate planned activities to reduce costs.

Coronavirus Pandemic

In March 2020, the World Health Organization declared the COVID-19 outbreak a pandemic. In order to mitigate the spread of COVID-19, governments have imposed unprecedented restrictions on business operations, travel and gatherings, resulting in a global economic downturn and other adverse economic and societal impacts. The COVID-19 pandemic has also overwhelmed or otherwise led to changes in the operations of many healthcare facilities, including clinical trial sites. We cannot predict the scope and severity of any further disruptions as a result of COVID-19 and continuing resource constraints or their impacts on CROs, us, clinical trial sites and others. Continuing resource constraints or business disruptions for us or any of the third parties with whom we engage, including the collaborators, contract organizations, third-party manufacturers, suppliers, clinical trial sites, regulators and other third parties with whom we conduct business could materially and negatively impact our ability to conduct our business in the manner and on the timelines presently planned. We are unable to determine the extent of the impact of the pandemic on our clinical trials, operations and financial condition going forward. These developments are highly uncertain and unpredictable, and may materially adversely affect our financial position and results of operations

Components of Operating Results

Operating Expenses

Our operating expenses since inception have consisted primarily of research and development expenses and general and administrative costs.

Research and Development

Our research and development expenses consist primarily of costs incurred for the development of our product candidates and our drug discovery efforts, which include:

- personnel costs, which include salaries, benefits and equity-based compensation expense;
- expenses incurred under agreements with outside consultants and advisors, including their fees and related travel expenses;
- expenses incurred under agreements with third parties, including CROs that conduct research, preclinical activities and clinical trials on our behalf as well as CMC manufacture our product candidates for use in our preclinical and clinical trials and perform chemistry, manufacturing and control activities (CMC); activities;
- laboratory and vendor expenses related to the execution of preclinical studies and planned and ongoing clinical trials;

- expenses related to research conducted by institutions, universities and hospitals as part of collaborations;
- filing and maintenance of patents and intellectual property rights, including payment to third parties for assignment of patent rights and licensing fees and mil payments incurred under product license agreements where no alternative future use exists;

- laboratory supplies and equipment used for internal research and development activities; and
- facility-related expenses, which include direct depreciation costs and allocated expenses for rent and maintenance of facilities and other operating costs.

We expense all research and development costs in the periods in which they are incurred. Costs for certain research and development activities are recognized based on an evaluation of the progress to completion of specific tasks using information and data provided to us by our vendors and third-party service providers.

From time to time, we obtain grants from public and private funds for our research and development projects. The grant income for a given period is recognized as a cost reimbursement and is typically based on the time and the costs that we have spent on the specific project during that period.

We have historically met the requirements to receive a tax credit in Denmark of up to 5.5 million Danish Kroner per year for tax losses resulting from research and development costs of up to 25 million Danish Kroner per year. The tax credit is presented as a reduction to research and development expense in the consolidated statements of operations.

We use our personnel and infrastructure resources across multiple research and development programs directed toward identifying and developing product candidates. We generally have not tracked our research and development expenses on a program-by-program basis. Substantially all of our direct research and development expenses in the years ended December 31, 2022 December 31, 2023 and 2021 2022 were on IO102-IO103 and consisted primarily of external costs, such as consultants, third-party contract organizations that conduct research and development activities on our behalf, costs related to production of preclinical and clinical materials, including fees paid to contract manufacturers, and laboratory and vendor expenses related to the execution of our ongoing and planned preclinical studies and clinical trials.

We expect our to incur significant research and development expenses to increase substantially for the foreseeable future as we continue to invest in research and development activities related to developing our product candidates, including investments in conducting clinical trials, manufacturing and otherwise advancing our programs. The process of conducting the necessary clinical research to obtain regulatory approval is costly and time-consuming, and the successful development of our product candidates is highly uncertain.

Because of the numerous risks and uncertainties associated with product development and the current stage of development of our product candidates and programs, we cannot reasonably estimate or know the nature, timing and estimated costs necessary to complete the remainder of the development of our product candidates or programs. We are also unable to predict if, when, or to what extent we will obtain approval and generate revenues from the commercialization and sale of our product candidates. The duration, costs and timing of preclinical studies and clinical trials and development of our product candidates will depend on a variety of factors, including:

- successful completion of preclinical studies and of clinical trials for IO102-IO103, IO112, IO170, and our other current product candidates and any future p candidates;
- successful enrollment and completion of our Phase 3 clinical trial for IO102-IO103, Phase 2 IO102-IO103 basket trials, and any clinical trials for future product candi
- data from our clinical programs that support an acceptable risk-benefit profile of our product candidates in the intended patient populations;
- acceptance by the FDA, regulatory authorities in Europe, or other regulatory agencies of the IND applications, clinical trial applications and/or other regulatory filii IO102-IO103, our other current product candidates and any future product candidates;
- expansion and maintenance of a workforce of experienced scientists and others to continue to develop our product candidates;
- successful application for and receipt of marketing approvals from applicable regulatory authorities;
- obtainment and maintenance of intellectual property protection and regulatory exclusivity for our product candidates;
- arrangements with third-party manufacturers for, or establishment of, commercial manufacturing capabilities;

- establishment of sales, marketing and distribution capabilities and successful launch of commercial sales of our products, if and when approved, whether alon collaboration with others;
- acceptance of our products, if and when approved, by patients, the medical community and third-party payors;
- effective competition with other therapies;
- obtainment and maintenance of coverage, adequate pricing and adequate reimbursement from third-party payors, including government payors;

- maintenance, enforcement, defense and protection of our rights in our intellectual property portfolio;
- avoidance of infringement, misappropriation or other violations with respect to others' intellectual property or proprietary rights; and
- maintenance of a continued acceptable safety profile of our products following receipt of any marketing approvals.

We may never succeed in achieving regulatory approval for any of our product candidates. We may obtain unexpected results from our preclinical studies and clinical trials. We may elect to discontinue, delay or modify clinical trials of some product candidates or focus on others. A change in the outcome of any of these factors could mean a significant change in the costs and timing associated with the development of our current and future preclinical and clinical product candidates. For example, if the FDA or another regulatory authority were to require us to conduct clinical trials beyond those that we currently anticipate will be required for the completion of clinical development, or if we experience significant delays in execution of or enrollment in any of our preclinical studies or clinical trials, we could be required to expend significant additional financial resources and time on the completion of preclinical and clinical development.

Research and development activities account for a significant portion of our operating expenses. We expect our to incur significant research and development expenses to increase for the foreseeable future as we continue to implement our business strategy, which includes advancing IO102-IO103 through clinical development and other product candidates further into clinical development, expanding our research and development efforts, including hiring additional personnel to support our research and development efforts, and seeking regulatory approvals for our product candidates that successfully complete clinical trials. In addition, product candidates in later stages of clinical development generally incur higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. As a result, we expect our research and development expenses to increase as our product candidates advance into later stages of clinical development. However, we do not believe that it is possible at this time to accurately project total program-specific expenses through commercialization. There are numerous factors associated with the successful commercialization of any of our product candidates, including future trial design and various regulatory requirements, many of which cannot be determined with accuracy at this time based on our stage of development.

General and Administrative Expenses

Our general and administrative expenses consist primarily of personnel costs, depreciation expense and other expenses for outside professional services, including legal fees relating to patent and corporate matters, human resources, audit and accounting services and facility-related fees not otherwise included in research and development expenses. Personnel costs consist of salaries, benefits and equity-based compensation expense, for our personnel in executive, finance and accounting, business operations and other administrative functions. We expect our to continue to incur significant general and administrative expenses to increase over the next several years to support our continued research and development activities, manufacturing activities, increased costs of expanding our operations and operating to continue to operate as a public company. These increases costs will likely include increases related to the hiring of additional retaining key personnel, fees to outside consultants, lawyers and accountants, and increased costs associated with being a public company such as expenses related to services associated with maintaining compliance with Nasdaq listing rules and SEC requirements, director and officer insurance premiums and investor relations costs.

Other Income (Expense), Net

Our other income (expense), net is comprised of:

- **Foreign exchange**: Our The functional currency of our subsidiaries operating in Denmark and United Kingdom is the Euro. Euro and the British Pound, respectively. Transactions denominated in currencies other than the Euro and the British Pound result in exchange gains and losses that are recorded in our consolidated statements of operations.
- **Fair value adjustments on convertible notes**: For the year ended December 31, 2021, we elected to account for our convertible notes at fair value, with corresponding adjustments to fair value accounted for as gains and losses

in our statements of operations. The convertible notes were settled immediately prior to the consumption of our IPO in November 2021.

- **Interest expense**: For the years year ended December 31, 2022 and 2021, , we incurred interest expense on account balances with banks and vendors. We did not incur interest expense for the year ended December 31, 2023.
- **Interest income**: For the years ended December 31, 2022 December 31, 2023 and 2021, 2022, we recognized interest income on account balances invested in money market funds and on account balances with banks.

Results of Operations

Comparison of the Years Ended December 31, 2022 December 31, 2023 and 2021 2022

The following sets forth our results of operations:

	Year Ended December 31,		Change		Year Ended December 31,		Change	
	2022	2021	Amount	Percent	2023	2022	Amount	Percent
	(in thousands)				(in thousands)			
Operating expenses								
Research and development	$ 46,986	$ 30,152	$ 16,834	55.8%	$ 67,829	$ 46,986	$ 20,843	44.4%
General and administrative	24,438	11,082	13,356	120.5%	23,614	24,438	(824)	(3.4)%
Total operating expenses	71,424	41,234	30,190	73.2%	91,443	71,424	20,019	28.0%
Loss from operations	(71,424)	(41,234)	(30,190)	73.2%	(91,443)	(71,424)	(20,019)	28.0%
Other income (expense), net	1,239	(26,577)	27,816	(104.7)%				
Net loss before income tax expense	$ (70,185)	$ (67,811)	$ (2,374)	3.5%				
Other income, net					6,212	1,239	4,973	401.4%
Loss before income tax expense					(85,231)	(70,185)	(15,046)	21.4%
Income tax expense					852	1,273	(421)	(33.1)%
Net loss					$ (86,083)	$ (71,458)	$ (14,625)	20.5%

Research and Development Expenses

Research and development expenses were comprised of:

	Year Ended December 31,		Change		Year Ended December 31,		Change	
	2022	2021	Amount	Percent	2023	2022	Amount	Percent
	(in thousands)				(in thousands)			
Preclinical studies and clinical trial-related activities	$ 19,910	$ 14,658	$ 5,252	35.8%	$ 33,716	$ 19,910	$ 13,806	69.3%
Chemistry, manufacturing and control	9,354	6,462	2,892	44.8%	14,865	9,354	5,511	58.9%
Personnel	15,101	7,403	7,698	104.0%	17,276	15,101	2,175	14.4%
Consultants and other costs	2,621	1,629	992	60.9%	1,972	2,621	(649)	(24.8)%
Total research and development expenses	$ 46,986	$ 30,152	$ 16,834	55.8%	$ 67,829	$ 46,986	$ 20,843	44.4%

Research and development expenses were $67.8 million for the year ended December 31, 2023, compared to $47.0 million for the year ended December 31, 2022, compared to $30.2 million for the year ended December 31, 2021. The increase of $16.8 million $20.8 million was primarily related to an increase in preclinical studies and clinical trial-related activities for our IO102-IO103 product therapeutic vaccine candidate, including the continued execution of our Phase 3 clinical trial, of $5.3 million $13.8 million, an increase in personnel costs of $7.7 million primarily related to an increase in headcount and related recruiting costs and an increase in costs for chemistry, manufacturing and control activities of $2.9 million $5.5 million related to manufacturing activities of our IO102-IO103 therapeutic product candidate and an increase in personnel costs of $2.2 million primarily related to a one time charge in equity-based compensation that were offset by a decrease in consultants and other costs of $0.6 million.

General and Administrative Expenses

General and administrative expenses were comprised of:

Year Ended December 31,		Change		Year Ended December 31,		Change	
2022	2021	Amount	Percent	2023	2022	Amount	Percent
(in thousands)				(in thousands)			

Personnel	$ 7,260	$ 2,956	$ 4,304	145.6%	$ 10,294	$ 7,260	$ 3,034	41.8%
Professional services	5,167	3,981	1,186	29.8%	4,469	5,167	(698)	(13.5)%
Consultants and other costs	12,011	4,145	7,866	189.8%	8,851	12,011	(3,160)	(26.3)%
Total general and administrative expenses	$ 24,438	$ 11,082	$ 13,356	120.5%	$ 23,614	$ 24,438	$ (824)	(3.4)%

General and administrative expenses were $23.6 million for the year ended December 31, 2023, compared to $24.4 million for the year ended December 31, 2022, compared to $11.1 million for the year ended December 31, 2021. The increase decrease of $13.4 million $0.8 million was primarily related due to an increase in personnel costs of $4.3 million primarily $3.0 million related to an increase in headcount and related recruiting costs and an increase head count that were offset by a decrease in consultants

and other costs of $7.9 million $3.2 million primarily related to $2.9 million a decrease in consultant spend and insurance premiums $2.3 million in consulting expense and $0.8 million in travel a decrease of professional services costs of $0.7 million primarily related to less professional service spend related to legal and accounting costs.

Other Income (Expense), Net

Other income (expense), net was comprised of:

	Year Ended December 31,		Change	
	2022	2021	Amount	Percent
	(in thousands)			
Net foreign exchange (loss) gain	$ 130	$ 319	$ (189)	(59.2)%
Interest income	1,411	—	1,411	100.0%
Interest expense	(302)	(361)	59	(16.3)%
Fair value adjustments on preferred stock tranche obligations	—	(26,535)	26,535	(100.0)%
Other income (expense), net	$ 1,239	$ (26,577)	$ 27,816	(104.7)%

	Year Ended December 31,		Change	
	2023	2022	Amount	Percent
	(in thousands)			
Currency exchange gain, net	$ 331	$ 130	$ 201	154.6%
Interest income	5,881	1,411	4,470	316.8%
Interest expense	—	(302)	302	(100.0)%
Other income, net	$ 6,212	$ 1,239	$ 4,973	401.4%

Other income (expense), net was $6.2 million for the year ended December 31, 2023 compared to $1.2 million for the year ended December 31, 2022 compared to ($26.6) million for the year ended December 31, 2021. The increase of $27.8 million $5.0 million was primarily due to the decrease an increase in the fair value adjustments interest income recognized on the Company's preferred stock tranche obligations. our money market fund.

Liquidity and Capital Resources

Sources of Liquidity

Our operations to date have been financed primarily by aggregate net proceeds of $288.7 million $360.6 million from the issuance of convertible preference shares, convertible notes, Class A ordinary shares, our IPO and most recently, our IPO. Private Placement. On August 9, 2023, we completed the Private Placement, pursuant to which we raised $71.9 million in net proceeds after deducting offering expenses of $3.2 million.

On November 9, 2021, we completed an IPO of our common stock and issued and sold 8,222,500 shares of common stock at a public offering price of $14.00 per share, including 1,072,500 shares of common stock sold pursuant to the underwriters' exercise of their option to purchase additional shares of common stock, resulting in net proceeds of

$103.3 million after deducting underwriting discounts and commissions and estimated offering expenses.

On August 7, 2023, the Company entered into the Purchase Agreement, pursuant to which the Company agreed to sell and issue (i) 37,065,647 shares of the Company's Common Stock, and (ii) 37,065,647 Warrants in the Private Placement. Each Purchaser's Warrant is exercisable for a number of shares of Common Stock equal to one hundred percent of the aggregate number of shares of Common Stock purchased by such Purchaser. The purchase price for each share of Common Stock and Warrant was $2.025. The Warrants are exercisable at an exercise price of $2.47 per share, subject to adjustment as set forth therein. The Warrants are exercisable until the earlier of (i) February 9, 2027, and (ii) one day prior to the closing of an acquisition, as defined in the Warrants. The Warrants may be exercised on a cashless basis if there is no effective registration statement registering the shares underlying the Warrants. The Private Placement closed on August 9, 2023. The Company received $75.1 million in gross proceeds from the Private Placement, before deducting offering expenses of $3.2 million. The Company intends to use the net proceeds of $71.9 million from the Private Placement for general corporate purposes.

In addition, on February 15, 2023, we filed a new prospectus supplement with the SEC with respect to the offer and sale of shares of our common stock, par value $0.001 per share, with an aggregate offering price of up to $19,500,000, establishing an at-the-market equity program. On February 15, 2023, we also entered into a Sales Agreement by and between the Company and Cowen and Company, LLC for shares with an aggregate offering price of up to $75,000,000 through which we may, from time to time, sell shares through Cowen and Company, LLC, acting as agent and/or principal. Any shares offered and sold through the at-the-market equity program will be issued pursuant to the Company's Registration Statement on Form S-3 (File No. 333-269569), which was declared effective on February 10, 2023, the prospectus supplement related to the offering that forms a part of the registration statement, and any applicable prospectus supplements that may form a part of the registration statement in the future. The aggregate market value of shares eligible for sale under the prospectus supplement and under the Sales Agreement will be subject to the limitations of General Instruction I.B.6 of Form S-3, to the extent required under such instruction. We have not currently issued any shares pursuant to our at-the-market equity program as of December 31, 2023.

Since inception, we have had significant operating losses. Our net loss was $71.5 million $86.1 million and $67.9 million $71.5 million for the years ended December 31, 2022 December 31, 2023 and 2021, 2022, respectively. As of December 31, 2022 December 31, 2023, we had an accumulated deficit of $177.7 million $263.8 million and $142.6 million $143.2 million in cash and cash equivalents. Our primary use of cash is to fund operating expenses, which consist primarily of research and development expenditures, and to a lesser extent, general and administrative expenditures. Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our outstanding accounts payable and accrued expenses.

We currently expect that our cash and cash equivalents of $142.6 million $143.2 million as of December 31, 2022 December 31, 2023 will be sufficient to fund our operating expenses and capital requirements through into the third fourth quarter of 2024. 2025. However, additional funding will be necessary to fund our future clinical and pre-clinical activities. If we are unable to obtain funding, we could be forced to delay, reduce or eliminate our research and development programs, product portfolio expansion or commercialization efforts, which could adversely affect our business prospects and our ability to continue operations.

Cash Flows

The following table summarizes our cash flows for the periods indicated:

	Year Ended December 31,		Year Ended December 31,	
	2022	2021	2023	2022
	(in thousands)		(in thousands)	
Net cash used in operating activities	$ (59,729)	$ (40,646)	$ (71,737)	$ (59,729)
Net cash used in investing activities	(690)	(153)	(323)	(690)
Net cash provided by financing activities	—	252,951	71,860	—
Net (decrease) increase in cash and cash equivalents	$ (60,419)	$ 212,152		
Net decrease in cash and cash equivalents			$ (200)	$ (60,419)

Net Cash Used in Operating Activities

Cash used in operating activities of $71.7 million during the year ended December 31, 2023 was primarily attributable to our net loss of $86.1 million, partially offset by an increase of $5.9 million in our working capital accounts and an increase in non-cash items of $8.5 million primarily due to equity-based compensation.

Cash used in operating activities of $59.7 million during the year ended December 31, 2022 was primarily attributable to our net loss of $71.5 million and a net, partially offset by an increase of $4.2 million in our working capital accounts partially offset by and an increase in non-cash items of $7.5 million primarily due to equity-based compensation.

Cash used in operating activities of $40.6 million during the year ended December 31, 2021 was primarily attributable to our net loss of $67.9 million and a net increase of $0.8 million in our working capital accounts, partially offset by non-cash items of $28.0 million primarily due to fair value adjustments on our preferred stock tranche obligations.

Net Cash Used in Investing Activities

Cash used in investing activities of $0.7 million $0.3 million and $0.2 million $0.7 million for the years ended December 31, 2022 December 31, 2023 and 2021, 2022, respectively, was related to the purchase of property and equipment.

Net Cash Provided by Financing Activities

Cash provided by financing activities of $71.9 million for the year ended December 31, 2023 was related to the net proceeds obtained from the issuance of common stock and warrants as part of the August 2023 private placement. We had no cash provided by financing activities for the year ended December 31, 2022.

Cash provided by financing activities for the year ended December 31, 2021 was $253.0 million comprised of $103.3 million of aggregate net proceeds from the issuance of common stock in our IPO in November 2021 and $149.6 million of net proceeds from the sale and issuance of our Class C convertible preference shares in January, March and October 2021. 132

Funding Requirements

Any product candidates we may develop may never achieve commercialization and we anticipate that we will continue to incur losses for the foreseeable future. We expect that our research and development expenses, general and administrative expenses, and capital expenditures will continue to increase. As a result, until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity offerings, debt financings or other capital sources, including potentially collaborations, licenses and other similar arrangements. Our primary uses of capital are, and we expect will continue to be, compensation and related expenses; costs related to third-party clinical research, manufacturing and development services; costs relating to the build-out of our headquarters and our other offices, laboratories and manufacturing facility; license payments or milestone obligations that may arise; laboratory expenses and costs for related supplies; clinical costs; manufacturing costs; legal and other regulatory expenses; and general overhead costs.

Based upon our current operating plan, we believe that our existing cash and cash equivalents of $142.6 million $143.2 million as of December 31, 2022 December 31, 2023 will be sufficient to continue funding our development activities through the third fourth quarter of 2024. 2025. To finance our operations beyond that point we will need to raise additional capital, which, though we were successful in raising additional capital through the Private Placement, cannot be assured. assured and which we may not be able to pursue successfully again in the future. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. We will continue to require additional financing to advance our current product candidates through clinical development, to develop, acquire or in-license other potential product candidates and to fund operations for the foreseeable future. We will continue to seek funds through equity offerings, debt financings or other capital sources, potentially including collaborations, licenses and other similar arrangements. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. If we do raise additional capital through public or private equity offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Any failure to raise capital as and when needed could have a negative impact on our financial condition and on our ability to pursue our business plans and strategies. If we are unable to raise capital, we may need to delay, reduce or terminate planned activities to reduce costs.

Because of the numerous risks and uncertainties associated with research, development and commercialization of pharmaceutical products, we are unable to estimate the exact amount of our operating capital requirements. Our future funding requirements will depend on many factors, including, but not limited to:

- the progress, costs and results of our ongoing and planned clinical trials of IO102-IO103, as well as our planned trials for our other product candidates;
- the scope, progress, results and costs of discovery research, preclinical development, laboratory testing and clinical trials for our product candidates, includi ongoing clinical trials of IO102-IO103;
- the impacts of the COVID-19 pandemic;
- the number of, and development requirements for, other product candidates that we pursue;
- the costs, timing and outcome of regulatory review of our product candidates;

- our ability to enter into contract manufacturing arrangements for supply of active pharmaceutical ingredient, or API, and manufacture of our product candidates a

terms of such arrangements;

- our ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of such arrangements;
- the payment or receipt of milestones and receipt of other collaboration-based revenues, if any;
- the costs and timing of any future commercialization activities, including product manufacturing, sales, marketing and distribution, for any of our product candida which we may receive marketing approval;
- the amount and timing of revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property and proprietary rights and defendi intellectual property-related claims;
- the extent to which we acquire or in-license other products, product candidates, technologies or data referencing rights;
- the enrollment for and completion of our upcoming Phase 3 registration clinical trial the IOB-013/KN-D18 trial; for IO102-IO103, Phase 2 basket trials, and any clinica for future product candidates;

- the ability to receive additional non-dilutive funding, including grants from organizations, public institutions and foundations;
- addition of operational, financial and management information systems and personnel, including personnel to support our drug development, any future commercial efforts and our transition to a public company; and
- the costs of operating as a public company.

Further, our operating plans may change, and we may need additional funds to meet operational needs and capital requirements for clinical trials and other research and development activities. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our current and anticipated product development programs.

Contractual Obligations and Commitments

In March 2021, we entered into a new lease for our office space in Copenhagen, Denmark that was amended in September 2022 and is set to expire in December 2027. The lease for our office space in Copenhagen, Denmark is terminable upon six months' months' notice. In January 2023, we entered into a lease for laboratory space in Copenhagen, Denmark that expires in December 2027. In August 2021, we entered into a new lease for laboratory facilities and office space in Rockville, Maryland that expires in April May 2027. In October 2021, we entered into a new lease for office space in New York, NY New York that expires in January 2027. In June 2023, we entered into a lease for office space in Newport, United Kingdom that expires in May 2025.

We enter into contracts in the ordinary course of business with third-party service providers for clinical trials, preclinical research studies and testing, manufacturing and other services and products for operating purposes. These contracts generally provide for termination upon notice of 30 to 90 days, and therefore, we believe that our non-cancelable obligations under these agreements are not material and we cannot reasonably estimate whether they will occur. However, in the event of a termination of any contracts with CROs or other institutions and with respect to active patients enrolled in our clinical trials, we may be financially obligated for a period beyond the contractual termination notice periods.

We may also enter into additional research, manufacturing, supplier, lease and other agreements in the future, which may require up-front payments and even long-term commitments of cash.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements, and the reported expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that

are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. We believe that the accounting policies discussed below are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates.

Going Concern

Our evaluation of our ability to continue as a going concern requires us to evaluate our future sources and uses of cash sufficient to fund our currently expected operations in conducting research and development activities. We evaluate the probability associated with each source and use of cash resources in making our going concern determination. The research and development of pharmaceutical products is inherently subject to uncertainty. We currently expect that our cash and cash equivalents of $142.6 million $143.2 million as of December 31, 2022 December 31, 2023 will be sufficient to fund our operating expenses and capital requirements for at least 12 months from the date the financial statements are issued.

Research and Development Costs

We incur substantial expenses associated with clinical trials. Accounting for clinical trials relating to activities performed by CMO's, CRO's and other external vendors requires management to exercise significant estimates in regard to the timing and accounting for these expenses. We estimate costs of research and development activities conducted by service providers, which include costs associated with the conduct of sponsored research, preclinical studies, contract manufacturing activities and pass-through costs. The diverse nature of services being provided under CRO and other arrangements, the different compensation arrangements that exist for each type of service and the lack of timely information related to certain clinical activities complicates the estimation of accruals for services rendered by CROs and other vendors in connection with clinical trials. We record the estimated costs of research and development activities based upon the estimated amount of services provided but not yet invoiced and include allocate these costs in the accrued and other current liabilities or prepaid expenses on the balance sheets and within research and development expense on the statements of operations. In estimating the duration of a clinical study, we evaluate the start-up treatment and wrap-up periods, compensation arrangements and services rendered attributable to each clinical trial. Fluctuations are regularly tested against payment plans and trial completion assumptions.

We estimate these costs based on factors such as estimates of the work completed and budget provided and in accordance with agreements established with our collaboration partners and third-party service providers. We make significant judgments and estimates in determining the accrued liabilities and prepaid expense balances in each reporting period. As actual costs become known, we adjust our accrued liabilities or prepaid expenses. We have not experienced any material differences between accrued costs and actual costs incurred since our inception.

Our expenses related to clinical trials are based on estimates of patient enrollment and related expenses at clinical investigator sites as well as estimates for the services received and efforts expended pursuant to contracts with multiple research institutions, CMOs and CROs that may be used to conduct and manage clinical trials, chemistry and testing and manufacturing services on our behalf. We generally accrue expenses related to clinical trials based on contracted amounts applied to the level of patient enrollment and activity. If timelines or contracts are modified based upon changes in the clinical trial protocol or scope of work to be performed, we modify our estimates of accrued expenses accordingly on a prospective basis.

Equity-based Compensation

We issued stock-based compensation awards through the granting of warrants and stock options, which generally vest over a four-year period. We issued 2,171,841 options with a weighted average exercise price of $2.02 to certain employees, board members and advisors during the year ended December 31, 2023. We issued 1,211,155 options with a weighted average exercise price of $5.34 to certain employees, board members and advisors during the year ended December 31, 2022. We In July 2023, we issued 2,306,478 warrants 348,153 options with a weighted average exercise price of $14.74 to certain employees, board members and advisors during $1.86 as separate inducement grants distinct from the year ended December 31, 2021. These warrants, and all previously issued warrants, were transferred to the 2021 Equity Plan in November 2021. We also issued 675,200 options with an exercise price of $14.00 under our 2021 Equity Plan during the year ended December 31, 2021. 2023 Inducement Award Plan.

We account for equity-based compensation in accordance with ASC 718, *Compensation-Stock Compensation* (ASC 718). In accordance with ASC 718, compensation cost is measured at estimated fair value and is included as compensation expense over the vesting period during which service is provided in exchange for the award. award on a straight-line basis. Vesting of the awards depend solely on service conditions required of the employee. The Company reverses any previously recognized compensation cost associated with forfeited awards in the period of the forfeiture occurs.

We use a Black-Scholes option pricing model to determine fair value of our warrants and options. The Black-Scholes option pricing model includes various assumptions, including the fair value of common shares, expected life of warrants and options, the expected volatility and the expected risk-free interest rate. These assumptions reflect our best estimates, but they involve inherent uncertainties based on market conditions generally outside our control. As a result, if other assumptions had been used, equity-based compensation cost could have been materially impacted. Furthermore, if we use different assumptions

for future grants, share-based compensation cost could be materially impacted in future periods.

We will continue to use judgment in evaluating the assumptions utilized for our equity-based compensation expense calculations on a prospective basis. In addition to the assumptions used in the Black-Scholes model, the amount of equity-based compensation expense we recognize in our financial statements includes warrant forfeitures as they occurred.

Income Taxes

Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases, and operating losses and tax credit carry forwards. Deferred tax assets and liabilities are measured using enacted statutory tax rates expected to apply to taxable income in the jurisdictions and years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date.

Based on the level of historical operating results and projections for the taxable income for the future, we have determined that it is more likely than not that our net deferred tax assets will not be realized. Accordingly, we have recorded a full valuation allowance to reduce our net deferred tax assets in IO Biotech ApS, IO Bio US, Inc and IO Biotech, Inc.

We recognize tax benefits from uncertain tax positions only if, based on the technical merits of the position, it is more likely than not that the tax positions will be sustained on examination by the tax authority. The tax benefits recognized in the financial statements from such positions are measured based on the largest amount that is more than 50% likely to be realized upon ultimate settlement. We recognize interest and penalties related to unrecognized tax benefits within the provision for taxes in our statements of operations and comprehensive loss.

We operate in Denmark and may be subject to audits from various tax authorities. Management's judgment is required in determining our provision for income taxes, our deferred tax assets and liabilities, liabilities for uncertain tax positions, and any valuation allowance recorded against our net deferred tax assets. We will monitor the extent to which our deferred tax assets may be realized and adjust the valuation allowance accordingly.

Warrants Issued in Connection with Sale of Common Stock

The Company accounts for warrants issued as a separable unit in connection with sale of common stock as either liability or equity in accordance with Accounting Standards Codification (ASC) 480-10, Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity (ASC 480-10) or ASC 815-40, Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock (ASC 815-40). Under ASC 480-10, warrants are considered liabilities if they are mandatorily redeemable and they require settlement in cash or other assets, or a variable number of shares. If warrants do not meet liability classification under ASC 480-10, the Company considers the requirements of ASC 815-40 to determine whether the warrants should be classified as liability or equity. If warrants do not require liability classification under ASC 815-40 or other applicable generally accepted accounting principles in the United States of America (U.S. GAAP) the warrants should be classified as equity.

The proceeds received from the sale of equity classified warrants and shares of common stock in a bundled transaction are allocated based on the relative fair values of warrants and shares with no changes in fair value of warrants recognized after the issuance date.

Recently Adopted Accounting Pronouncements

Refer to Note 2, "Summary of Significant Accounting Policies," in the accompanying notes to our financial statements for the years ended December 31, 2022 December 31, 2023 and 2021 2022 appearing elsewhere in this Annual Report on Form 10-K for a discussion of recently issued accounting standards.

Off-Balance Sheet Arrangements

During the periods presented, we did not have, nor do we currently have, any off-balance sheet arrangements as defined under SEC rules.

Emerging Growth Company Status

As an EGC under the Jumpstart Our Business Startups (the JOBS Act, Act), we may delay the adoption of certain accounting standards until such time as those standards apply to private companies. We have elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date we (1) are no longer an emerging growth company or (2) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, our consolidated financial statements may not be comparable to companies that comply with new or revised accounting pronouncements as of public company effective dates.

Other exemptions and reduced reporting requirements under the JOBS Act for EGCs include presentation of only two years of audited financial statements in a registration statement for an IPO and in an Annual Report on Form 10-K, an exemption from the requirement to provide an auditor's report on internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act, an exemption from any requirement that may be adopted by the Public Company Accounting Oversight Board (PCAOB) regarding mandatory audit firm rotation, and less extensive disclosure about our executive compensation arrangements.

We may remain classified as an EGC until December 31, 2026, although if the market value of our common stock that is held by non-affiliates exceeds $700 million as of June 30 of any year before that time, or if we have annual gross revenues of $1.235 billion or more in any fiscal year, we would cease to be an EGC as of December 31 of the applicable year. We also would cease to be an EGC if we issue more than $1.0 billion of non-convertible debt over a three-year period.

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

We are a smaller reporting company as defined by Item 10 of Regulation S-K and are not required to provide the information otherwise required under this item.

Item 8. Financial Statements and Supplementary Data.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

IO BIOTECH, INC.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and the Board of Directors of IO Biotech, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of IO Biotech, Inc. (the Company) as of December 31, 2022 December 31, 2023 and 2021, 2022, the related consolidated statements of operations and comprehensive loss, convertible preference shares and stockholders' equity (deficit) and cash flows for each of the two years in the period ended December 31, 2022 December 31, 2023, 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, 2022 December 31, 2023 and 2021, 2022, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2022 December 31, 2023, in conformity with U.S. generally accepted accounting principles.

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 Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

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

Our audits included performing procedures to assess the risks of material misstatement of the 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.

/s/ EY Godkendt Revisionspartnerselskab

We have served as the Company's auditor since 2015.

Copenhagen, Denmark
March 14, 2023 5, 2024

IO BIOTECH, INC.

Consolidated Balance Sheets

(In thousands, except share and per share amounts)

	December 31,		December 31,	
	2022	2021	2023	2022
Assets				
Current assets				

Cash and cash equivalents	14	21		
	2,5	1,5		
	$ 90	$ 31	$ 143,193	$ 142,590
Prepaid expenses and other current assets		10,		
	5,6	20		
	29	7	4,062	5,629
Total current assets	14	22		
	8,2	1,7		
	19	38	147,255	148,219
Restricted cash	26	26		
	8	8	268	268
Property and equipment, net	74	15		
	1	5	847	741
Right of use lease asset	2,4			
	93	—	2,259	2,493
Other non-current assets		12		
	84	7	89	84
Total non-current assets	3,5	55		
	86	0	3,463	3,586
Total assets	15	22		
	1,8	2,2		
	$ 05	$ 88	$ 150,718	$ 151,805
Liabilities, convertible preference shares and stockholders' equity				
Liabilities and stockholders' equity				
Current liabilities				
Accounts payable	4,0	3,9		
	$ 04	$ 28	$ 3,878	$ 4,004
Lease liability - current	51			
	5	—	655	515
Accrued expenses and other current liabilities	6,1	6,3		
	57	77	11,184	6,157
Total current liabilities	10,	10,		
	67	30		
	6	5	15,717	10,676
Lease liability - noncurrent	2,2			
	75	—		
Other long-term liabilities	—	59		
Lease liability - non-current			1,839	2,275
Total non-current liabilities	2,2			
	75	59	1,839	2,275
Total liabilities	12,	10,		
	95	36		
	1	4	17,556	12,951
Commitments and contingencies (Note 9)				
Convertible preference shares	—	—		
Stockholders' equity				
Preferred stock, par value of $0.001 per share; 5,000,000 shares authorized, no shares issued and outstanding as of December 31, 2022 and 2021	—	—		
Common stock, par value of $0.001 per share; 300,000,000 shares authorized, 28,815,267 shares issued and outstanding as of December 31, 2022 and December 31, 2021, respectively	29	29		
Preferred stock, par value of $0.001 per share; 5,000,000 shares authorized, no shares issued and outstanding as of December 31, 2023 and 2022			—	—

Common stock, par value of $0.001 per share; 300,000,000 shares authorized at December 31, 2023 and December 31, 2022; 65,880,914 and 28,815,267 shares issued and outstanding as of December 31, 2023 and December 31, 2022, respectively	66	29
Additional paid-in capital	406,587	326,705
Accumulated deficit	(263,822)	(177,739)
Accumulated other comprehensive loss	(9,669)	(10,141)
Total stockholders' equity	133,162	138,854
Total liabilities, convertible preference shares and stockholders' equity		
Total liabilities and stockholders' equity	$ 150,718	$ 151,805

See accompanying notes to the consolidated financial statements.

IO BIOTECH, INC

Consolidated Statements of Operations and Comprehensive Loss

(In thousands, except share and per share amounts)

	Year Ended December 31,		Year Ended December 31,	
	2022	2021	2023	2022
Operating expenses				
Research and development	$ 46,986	$ 30,152	$ 67,829	$ 46,986
General and administrative	24,438	11,082	23,614	24,438
Total operating expenses	71,424	41,234	91,443	71,424
Loss from operations	(71,424)	(41,234)	(91,443)	(71,424)
Other income (expense)				
Currency exchange gain, net	130	319	331	130
Interest income	1,411	—	5,881	1,411
Interest expense	(302)	(361)	—	(302)
Fair value adjustments on preference shares tranche obligations	—	(26,535)		
Total other income (expense), net	1,239	(26,577)		
Total other income, net			6,212	1,239
Loss before income tax expense	(70,185)	(67,811)	(85,231)	(70,185)
Income tax expense	1,273	68	852	1,273
Net loss	(71,458)	(67,879)	(86,083)	(71,458)
Cumulative dividends on class B and C preference shares	—	(7,108)		
Net loss attributable to common shareholders	(71,458)	(74,987)	(86,083)	(71,458)

Net loss per common share, basic and diluted	$ (2.48)	$ (17.30)	$ (1.98)	$ (2.48)
Weighted-average number of shares used in computing net loss per common share, basic and diluted	28,815,267	4,335,629	43,539,976	28,815,267
Other comprehensive loss				
Net loss	(71,458)	(67,879)	$ (86,083)	$ (71,458)
Foreign currency translation	(8,652)	(3,450)	472	(8,652)
Total comprehensive loss	$ (80,110)	$ (71,329)	$ (85,611)	$ (80,110)

See accompanying notes to the consolidated financial statements.

IO BIOTECH, INC.

Consolidated Statements of Convertible Preference Shares and Stockholders' Equity (Deficit)

(In thousands, except share amounts)

	Class B Convertible Preference Shares		Class C Convertible Preference Shares		Common Stock		Class A Ordinary Shares		Additional Paid-In Capital	Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity (Deficit)	Common Stock		Additional Paid-In	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount					Shares	Amount	Capital	Loss	Deficit	Equity
Balance, January 1, 2021	584,583	37,906	—	—	—	—	177,200	28	1,110	1,961	(38,402)	(35,303)						
Issuance of class C preference shares, net of issuance costs of $340 and adjusted for settlement of tranche obligation of $28,276 of which $25,908 is non-cash	—	—	1,194,864	175,509	—	—	—	—	—	—	—	—						
Issuance of common stock	—	—	—	—	354	—	—	—	—	—	—	—						
Exchange of preferred and ordinary shares of IO Biotech ApS into common stock of IO Biotech, Inc.	(584,583)	(37,906)	(1,194,864)	(175,509)	20,592,413	21	(177,200)	(28)	213,422	—	—	213,415						

Issuance of common stock in connection with initial public offering, net of issuance costs of $11,765	—	—	—	—	8,222,500	8	—	—	10,323,435	—	—	10,323,435		
Equity-based compensation	—	—	—	—	—	—	—	—	1,791	—	—	1,791		
Foreign currency translation	—	—	—	—	—	—	—	—	—	(3,450)	—	(3,450)		
Net loss	—	—	—	—	—	—	—	—	—	—	(6,787,879)	(6,787,879)		
Balance, December 31, 2021	—	$ —	—	$ —	28,815,267	$ 29	—	$ —	$ 5,319,665	$ (1,489)	$ (106,281)	$ 5,211,924		
Balance, January 1, 2022					28,815,267	29			319,665	(1,489)	(106,281)	211,924		
Equity-based compensation	—	—	—	—	—	—	—	—	7,040	—	—	7,040		
Foreign currency translation	—	—	—	—	—	—	—	—	—	(8,652)	—	(8,652)		
Net loss	—	—	—	—	—	—	—	—	—	—	(71,458)	(71,458)		
Balance, December 31, 2022	—	$ —	—	$ —	28,815,267	$ 29	—	$ —	$ 326,705	$ (10,141)	$ (177,739)	$ 138,854		
Equity-based compensation					—	—			8,059	—	—	8,059		
Foreign currency translation					—	—			—	472	—	472		
Issuance of common shares and warrants in private placement, net of issuance costs of $3,198					37,065,647	37			71,823		—	71,860		
Net loss					—	—			—	—	(86,083)	(86,083)		
Balance, December 31, 2023					65,880,914	$ 66			$ 406,587	$ (9,669)	$ (263,822)	$ 133,162		

See accompanying notes to the consolidated financial statements.

IO BIOTECH, INC.

Consolidated Statements of Cash Flows

(In thousands)

	Year Ended December 31,		Year Ended December 31,	
	2022	2021	2023	2022
Cash flows from operating activities				
Net loss	($ 71,458)	($ 67,879)	($ 86,083)	($ 71,458)
Adjustment to reconcile net loss to net cash used in operating activities				
Depreciation	104	2	215	104
Equity-based compensation	7,040	1,791	8,059	7,040
Fair value adjustments preference shares tranche obligations	—	26,535		
Amortization of right of use lease asset	436	—	541	436
Foreign currency gain	(130)	(319)	(331)	(130)
Provision for deferred tax	87	—	—	87
Changes in operating assets and liabilities				
Prepaid expenses and other current assets	4,578	(8,090)	1,568	4,578
Other noncurrent assets	(44)	(25)		
Other non-current assets			(4)	(44)
Accounts payable	77	3,406	(126)	77
Lease liability	(139)	—	(604)	(139)
Accrued expenses and other current liabilities	(280)	3,933	5,028	(280)
Net cash used in operating activities	(59,729)	(40,646)	(71,737)	(59,729)
Cash flows from investing activities				
Purchase of property and equipment	(690)	(153)	(323)	(690)
Net cash used in investing activities	(690)	(153)	(323)	(690)
Cash flows from financing activities				
Proceeds from issuance of preference shares	—	149,941		
Preference share issuance costs	—	(340)		
Proceeds from issuance of common stock	—	115,115		
Common stock issuance costs	—	(11,765)		
Proceeds from issuance of common shares and warrants			75,058	—
Common shares and warrants issuance costs			(3,198)	—
Net cash provided by financing activities	—	252,951	71,860	—

Net (decrease) increase in cash, cash equivalents and restricted cash	(60,419)	212,152		
Net decrease in cash, cash equivalents and restricted cash			(200)	(60,419)
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(8,522)	(3,758)	803	(8,522)
Cash, cash equivalents and restricted cash, beginning of year	211,799	3,405	142,858	211,799
Cash, cash equivalents and restricted cash, end of year	142,858	211,799	$ 143,461	$ 142,858
Components of cash, cash equivalents, and restricted cash				
Cash and cash equivalents	142,590	211,531	143,193	142,590
Restricted cash	268	268	268	268
Total cash, cash equivalents, and restricted cash	142,858	211,799	$ 143,461	$ 142,858
Supplemental disclosures of non-cash financing activities:				
Exchange of preferred and ordinary shares of IO Biotech ApS into common stock of IO Biotech, Inc. upon closing of initial public offering	$ —	213,443		
Non-cash portion of settlement of preference shares tranche obligation	$ —	25,908		

See accompanying notes to the consolidated financial statements.

IO BIOTECH, INC.

Notes to the Consolidated Financial Statements

1. Description of Business, Organization and Liquidity

Business

IO Biotech, Inc. is a clinical-stage biotechnology biopharmaceutical company dedicated to the identification and development of disruptive immune therapies for the treatment of cancer. developing novel, immune-modulating therapeutic cancer vaccines based on our T-win® platform. As used in these financial statements, unless the context otherwise requires, references to the "Company", "Company," "we," "us," and "our" refer to IO Biotech, Inc. and its subsidiaries.

Corporate reorganization

IO Biotech ApS was incorporated in Denmark in December 2014. We are developing novel, immune-modulating cancer vaccines based on our T-win technology platform.

Corporate reorganization

In November 2021, we completed a corporate reorganization whereby IO Biotech ApS became a wholly-owned subsidiary of the Company. In connection with the corporate reorganization, each issued and outstanding Class A ordinary share ($0.16 par value) was exchanged on a one for one one-for-one basis into shares of common stock of the Company ($0.001 par value). Each Class B and Class C preference share of IO Biotech ApS was exchanged on a one for one one-for-one basis into shares of Class B and Class C preferred stock of the Company.

IO Bio US, Inc., a wholly owned subsidiary of IO Biotech ApS, was incorporated in Delaware in May 2021. IO Biotech Limited, a wholly owned subsidiary of IO Biotech ApS, was incorporated in the UK in August 2021. In November 2021, the Company engaged in a series of transactions, referred to collectively as the Corporate Reorganization. As a result of the Corporate Reorganization, IO Biotech ApS became a wholly-owned subsidiary of IO Biotech, Inc. IO Biotech, Inc. is a holding company formed in October 2021, which, prior to our IPO, had nominal assets and no liabilities, contingencies, or commitments, and which has not conducted any operations prior to our IPO other than acquiring the entire issued and outstanding stock of IO Biotech ApS. The Company, IO Biotech ApS, and the holders of all of the issued and outstanding equity interests of IO Biotech ApS have entered into a Share Contribution and Exchange Agreement, dated as of October 29, 2021, pursuant to which the Corporate Reorganization was effected.

Initial Public Offering ("IPO")(IPO)

In November 2021, we completed our IPO, selling an aggregate of 8,222,500 shares of common stock at a price to the public of $14.00 per share, including 1,072,500 shares of common stock sold pursuant to the underwriters' exercise of their option to purchase additional shares of common stock. We received net proceeds from the IPO, after deducting underwriting discounts and commissions and other offering costs, of approximately $103.3 million.

Immediately prior to the consummation of the IPO, all outstanding shares of our class Class A ordinary shares and class Class B and class Class C convertible preference shares were converted into 20,592,413 shares of common stock. Upon the closing of the IPO on November 9, 2021, a total of 28,815,267 shares of common stock were issued and outstanding. Our common stock began trading on the Nasdaq Global Market on November 5, 2021 under the symbol "IOBT"."IOBT."

On November 9, 2021, we amended and restated the certificate of incorporation of IO Biotech, Inc. to authorize the issuance of 300,000,000 shares of common stock and 5,000,000 shares of preferred stock. The shares of preferred stock are currently undesignated.

August 2023 Private Placement

On August 9, 2023, the Company completed a private placement transaction (the Private Placement), pursuant to which we sold an aggregate of 37,065,647 shares of the Company's common stock, par value $0.001 per share, and 37,065,647 warrants to purchase up to 37,065,647 shares of common stock (the Warrants) to certain institutional investors and existing shareholders (the Purchasers). Each Purchaser's Warrant is exercisable for a number of shares of common stock equal to one hundred percent of the aggregate number of shares of common stock purchased by such Purchaser. The purchase price per share of common stock and Warrant was $2.025 (the Purchase Price). The Company received net proceeds from the Private Placement, after deducting $3.2 million in underwriting discounts and commissions and other offering costs, of $71.9 million. Refer to Note 2, "Summary of Significant Accounting Policies," and Note 10, "Stockholders' Equity" in the accompanying notes to our consolidated financial statements for the years ended December 31, 2023 and 2022 for additional information on the Private Placement.

At-The-Market Equity Program

On February 15, 2023, we filed a new prospectus supplement with the U.S. Securities and Exchange Commission (the SEC) with respect to the offer and sale of shares of our common stock, with an aggregate offering price of up to $19,500,000, establishing an at-the-market equity program. On February 15, 2023, we also entered into a common stock sales agreement, dated February 15, 2023 (the "Sales Agreement") by and between the Company and Cowen and Company, LLC for shares with an aggregate offering price of up to $75,000,000 through which we may, from time to time, sell shares through Cowen and Company, LLC, acting as agent and/or principal. Any shares offered and sold through the at-the-market equity program will be issued pursuant to the Company's Registration Statement on Form S-3 (File No. 333-269569), which was declared effective on February 10, 2023, the prospectus supplement related to the offering that forms a part of the registration statement, and any applicable prospectus supplements that may form a part of the registration statement in the future. The aggregate market value of shares eligible for sale under the prospectus supplement and under the Sales Agreement will be subject to the limitations of General Instruction I.B.6 of Form S-3, to the extent required under such instruction. We have not issued any shares pursuant to our at-the-market equity program as of December 31, 2023.

Risks and Uncertainties

We are subject to risks common to companies in the biotechnology industry including, but not limited to, new technological innovations, protection of proprietary technology, dependence on key personnel, compliance with government regulations and the need to obtain additional financing. Product candidates currently under development will require significant additional research and development efforts, including extensive pre-clinical and clinical testing and regulatory approval, prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel infrastructure and extensive compliance reporting capabilities.

Our product candidates are in preclinical research and clinical development. There can be no assurance that our research and development will be successfully completed, that adequate protection for our intellectual property will be obtained, that any products developed will obtain necessary government regulatory approval or that any approved products will be commercially viable. Even if our product development efforts are successful, it is uncertain when, if ever, we will generate significant revenue from product sales. We operate in an environment of rapid change in technology and substantial competition from pharmaceutical and biotechnology companies. In addition, we are dependent upon the services of our employees and consultants.

Liquidity Considerations and Going Concern Basis of Accounting

Since inception, we have devoted substantially all of our efforts to business planning, conducting research and development, recruiting management and technical staff, and raising capital. We have financed our operations primarily through the issuance of convertible preference shares, convertible notes, our IPO and most recently, our IPO.

the Private Placement.

Our continued discovery and development of product candidates will require significant additional research and development efforts, including extensive preclinical and clinical testing and regulatory approval prior to commercialization commercialization. These efforts require significant amounts of additional capital, adequate personnel and infrastructure and extensive compliance-reporting capabilities. Even if our product development efforts are successful, it is uncertain when, if ever, we will realize significant revenue from product sales.

As of December 31, 2022 December 31, 2023, we had an accumulated deficit of $177.7 263.8 million. We have incurred losses and negative cash flows from operations since inception, including net losses of $71.5 86.1 million and $67.9 71.5 million for the years ended December 31, 2022 December 31, 2023 and 2021, 2022, respectively. We expect that our operating losses and negative cash flows will continue for the foreseeable future as we continue to develop our product candidates. We currently expect that our cash and cash equivalents of $142.6 143.2 million as of December 31, 2022 December 31, 2023 will be sufficient to fund our operating expenses and capital requirements for at least 12 months from the date the financial statements are issued. On this basis the financial statements are prepared on a going concern basis of accounting. However, additional funding will be necessary to fund future discovery research, pre-clinical and clinical activities. We will seek additional funding through public financings, debt financings, collaboration agreements, strategic alliances and licensing arrangements. Although we have been successful in raising capital in the past, there is no assurance that we will be successful in obtaining such additional financing on acceptable terms, or at all, and we may not be able to enter into collaborations or other arrangements. If we are unable to obtain funding, we could be forced to delay, reduce or eliminate our research and development programs, product portfolio expansion or commercialization efforts, which could adversely affect our business prospects, even our ability to continue operations.

Coronavirus Pandemic

In March 2020, the World Health Organization declared the COVID-19 outbreak a pandemic. In order to mitigate the spread of COVID-19, governments have imposed unprecedented restrictions on business operations, travel and gatherings, resulting in a global economic downturn and other adverse economic and societal impacts. The COVID-19 pandemic has also overwhelmed or otherwise led to changes in the operations of many healthcare facilities, including clinical trial sites. We cannot predict the scope and severity of any further disruptions as a result of COVID-19 and continuing resource constraints or their impacts on CROs, us, clinical trial sites and others. But continuing resource constraints or business disruptions for us or any of the third parties with whom we engage, including the collaborators, contract organizations, third-party manufacturers, suppliers, clinical trial sites, regulators and other third parties with whom we conduct business could materially and negatively impact our ability to conduct our business in the manner and on the timelines presently planned.

The actual and perceived impact of the COVID-19 pandemic is changing daily, and its ultimate effect on our business cannot be predicted. As a result, there can be no assurance that we will not experience additional negative impacts associated with COVID-19, which could be significant. The COVID-19 pandemic may negatively impact our business, financial condition and results of operations causing interruptions or delays in the Company's programs and services.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying consolidated financial statements have been prepared in conformity with generally accepted accounting principles in the United States (U.S. GAAP). Any reference in these notes to applicable guidance is meant to refer to U.S. GAAP, as found in the Accounting Standards Codification (ASC) and Accounting Standards Update (ASU) of the Financial Accounting Standards Board (FASB).

Prior to the completion of our IPO, we approved a 3.544-for-1 stock split of our common stock. All share and per share amounts in the balance sheet and notes thereto have been retroactively adjusted for all periods presented to give effect to this split.

Principles of Consolidation

The Company's consolidated financial statements include the accounts of its subsidiaries IO Biotech ApS, IO Bio US, Inc. and IO Biotech Limited. IO Bio US, Inc., is a wholly owned subsidiary of IO Biotech ApS, was incorporated in Delaware in May 2021. ApS. IO Biotech Limited is a wholly owned subsidiary of IO Biotech ApS, was incorporated in the UK in August 2021. In November 2021, the Company engaged in a series of transactions, referred to collectively as the Corporate Reorganization. As a result of the Corporate Reorganization, IO Biotech ApS became a wholly-owned subsidiary of IO Biotech, Inc. and accordingly, our consolidated financial statements are those of IO Biotech, Inc. for the periods after the date of the Corporate Reorganization. IO Biotech, Inc. is a holding company formed in October 2021, which, prior to our IPO, had nominal assets and no liabilities, contingencies, or commitments, and which has not conducted any operations prior to our IPO other than acquiring the entire issued and outstanding stock of IO Biotech ApS. The Company, IO Biotech ApS, and the holders of all of

the issued and outstanding equity interests of IO Biotech ApS have entered into a Share Contribution and Exchange Agreement, dated as of October 29, 2021, pursuant to which the Corporate Reorganization was effected. Management has concluded it has a single reporting segment for purposes of reporting financial condition and results of operations. All intercompany transactions and balances have been eliminated.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires us to make estimates and assumptions that affect certain reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of expenses during the reporting periods. Significant items subject to such estimates and assumptions include contract research organization accruals, the fair value of stock-based compensation awards, the fair value of Warrants issued as part of the Private Placement and valuation of the Company's deferred tax assets. We base our estimates on historical experience and various other assumptions that we believe to be reasonable under the circumstances. Changes in estimates are recorded in the period in which they become known. Actual results could differ from those estimates.

Currency and Currency Translation

The financial statements are presented in U.S. dollars. Dollars, our reporting currency. The functional currency of IO Biotech ApS and IO Biotech Limited is the Euro. Euro and the British Pound, respectively. The functional currency of IO Bio US, Inc. and IO Biotech, Inc. is the U.S. Dollar. Adjustments that arise from exchange rate changes on transactions denominated in a currency other than the functional currency are included in other income and expense in the consolidated statements of operations. Assets and liabilities recorded in our Euro and British Pound functional currency currencies are translated into the U.S. dollar reporting currency at the exchange rate on the balance sheet date. Our expenses in the Euro and the British Pound functional currency currencies are translated into the U.S. dollar Dollar reporting currency at the average exchange rate prevailing during the year. each month. Resulting translation adjustments are recorded to other comprehensive income (loss) (OCI).

Cash and Cash Equivalents

The Company considers all highly liquid investments with an original maturity of three months or less at the date of purchase to be cash equivalents. Cash equivalents, which consist of money market accounts, are stated at fair value. As of December 31, 2022 December 31, 2023 and 2021 2022 we had money market funds of $88.0 131.6 million and $101.6 88.0 million, respectively, which are included in cash and cash equivalents and reported at fair value (Note 3).

Concentrations of Credit Risk and Off-Balance Sheet Risk

We maintain our cash in bank deposit and checking accounts that at times exceed insured limits. We have not experienced any losses in such accounts and believe we are not exposed to any significant credit risk, however, we are exposed to the potential loss of uninsured deposits should a financial institution we maintain our cash deposits with fail.

Fair Value of Financial Instruments

Fair value is defined as the price we would receive to sell an investment in a timely transaction or pay to transfer a liability in a timely transaction with an independent buyer in the principal market, or in the absence of a principal market, the most advantageous market for the investment or liability. A framework is used for measuring fair value utilizing a three-tier hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1) and the lowest priority to unobservable inputs (Level 3).

The three levels of the fair value hierarchy are as follows:

Level 1—Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities;

Level 2—Quoted prices in markets that are not considered to be active or financial instrument valuations for which all significant inputs are observable, either directly or indirectly; and

Level 3—Prices or valuations that require inputs that are both significant to the fair value measurement and unobservable.

Financial instruments are categorized in their entirety based on the lowest level of input that is significant to the fair value measurement. The assessment of the significance of a particular input to the fair value measurement requires judgment and considers factors specific to the investment. To the extent that the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by us in determining fair value is greatest for instruments categorized in Level 3.

We monitor the availability of inputs that are significant to the measurement of fair value to assess the appropriate categorization of financial instruments within the fair value hierarchy. Changes in economic conditions or model-based valuation techniques may require the transfer of financial instruments from one fair value level to another. In such instances, our policy is to recognize significant transfers between levels at the end of the reporting period. The significance of transfers between levels is evaluated based upon the nature of the financial instrument and size of the transfer relative to total net assets. As of December 31, 2022 December 31, 2023 and 2021, 2022, the Company only held Level 1 financial instruments, respectively.

Property and Equipment, net

Property and equipment consists of laboratory equipment, computer hardware and office furniture and are recorded at cost. Maintenance and repairs that do not improve or extend the lives of the respective assets are expensed as incurred. Property and equipment are depreciated on a straight-line basis over their estimated useful lives. The Company estimates useful life on an asset by asset basis, which generally consists of three years for computer hardware, five years for office furniture and five years for laboratory equipment.

The Company reviews long-lived assets, such as property and equipment, for impairment when events or changes in circumstances indicate the carrying amount of the assets may not be recoverable. If circumstances require a long-lived asset to be tested for possible impairment, recoverability is measured by comparison of the carrying amount of the assets to estimated future undiscounted cash flows that the assets are expected to generate. If the carrying amount of an asset exceeds its estimated future cash flows, then impairment expense is recognized for the amount by which the carrying amount of the asset exceeds the fair value of the asset. For the years ended December 31, 2022 December 31, 2023 and 2021, 2022, no impairment expenses were recognized.

Research and Development Expenses

Research and development costs are expensed as incurred. The Company's research and development expenses consist primarily of costs incurred for the development of its product candidates and include expenses incurred under agreements with contract manufacturing organizations, or CMOs, contract research organizations, or CROs, investigative sites and consultants to conduct clinical trials and preclinical and non-clinical studies, costs to acquire, develop and manufacture supplies for clinical trials and other studies, salaries and related costs, including equity-based compensation, depreciation and other allocated facility-related and overhead expenses and licensing fees and milestone payments incurred under product license agreements where no alternative future use exists.

We may obtain grants from public and private funds for our research and development projects. The grant income for a given period is recognized as a cost reimbursement and is typically based on the time and the costs that we have spent on the specific project during that period. During the years ended December 31, 2022 December 31, 2023 and 2021, 2022, we had active cost reimbursement grants with Innovation Fund Denmark. The grants provided partial reimbursement of employment-related costs related to two employees pursuant to Business Ph.D. and Business post-doctoral programs. For the years ended December 31, 2022 December 31, 2023 and 2021, 2022, research and development expenses in the statements of operations include $0.03 0.02 million and $0.1 0.03 million, respectively, of grant income cost reimbursement.

We have historically met the requirements to receive a tax credit in Denmark of up to 5.5 million Danish Kroner per year for tax losses resulting from research and development costs of up to 25.0 million Danish Kroner per year. The tax credit is reported as a reduction to research and development expense in the statements of operations. For the years ended December 31, 2022 December 31, 2023 and 2021, 2022, research and development expenses include refundable tax credits of $0.8 million, respectively.

Accrued Research and Development Costs

Substantial portions of our pre-clinical and clinical trials are performed by third-party laboratories, medical centers, CMOs, CROs and other vendors. These vendors generally bill monthly for services performed, or bill based upon milestone achievement. For preclinical studies, we accrue expenses based upon estimated percentage of work completed and the contract milestones remaining. For clinical studies, expenses are accrued based upon the number of patients enrolled, the duration of the study and other investigative costs. We monitor patient enrollment, the progress of clinical studies and related activities to the extent possible through internal reviews of data reported to us by the CROs, correspondence with the CROs and clinical site visits. Our estimates depend on the timeliness and accuracy of the data provided by the CROs regarding the status of each program and total program spending. We periodically evaluate the estimates to determine if adjustments are necessary or appropriate based on information we receive.

Leases

In February 2016, the FASB issued ASU No. 2016-02, *Leases* ("ASC 842") to enhance the transparency and comparability of financial reporting related to leasing arrangements. Under this new lease standard, most leases are required to

be recognized on the balance sheet as right-of-use (ROU) assets and lease liabilities. Disclosure requirements have been enhanced with the objective of enabling financial statement users to assess the amount, timing, and uncertainty of cash flows arising from leases. Prior to January 1, 2019, U.S. GAAP did not require lessees to recognize assets

and liabilities related to operating leases on the balance sheet. The new standard establishes a right-of-use model that requires a lessee to recognize a ROU asset and corresponding lease liability on the balance sheet for all leases with a term longer than 12 months. Leases will be are classified as finance or operating, with classification affecting the pattern and classification of expense recognition in the income statement as well as the reduction of the right of use asset. The In 2022, the Company has adopted the standard effective January 1, 2022 and has chosen chose to use the effective date as our date of initial application. Consequently, financial information will not be updated and the disclosures required under the new standard will not be provided for dates and periods prior to January 1, 2022. The new standard provides a number of optional practical expedients in transition. The Upon adoption, the Company has elected to apply the 'package of practical expedients' which allow allowed the Company to not reassess (1) whether existing or expired arrangements contain a lease; (2) the lease classification of existing or expired leases; or (3) whether previous initial direct costs would qualify for capitalization under the new lease standard. The Company has also elected to apply (1) the practical expedient which allows us to not separate lease and non-lease components, for new leases entered into after adoption and (2) the short-term lease exemption for all leases with an original term of less than 12 months, for purposes of applying the recognition and measurements requirements in the new standard.

At the inception of an arrangement, the Company determines whether the arrangement is or contains a lease based on specific facts and circumstances, the existence of an identified asset(s), if any, and the Company's control over the use of the identified asset(s), if applicable. Operating lease liabilities and their corresponding ROU assets are recorded based on the present value of future lease payments over the expected lease term. The interest rate implicit in lease contracts is typically not readily determinable. As such, the Company will utilize the incremental borrowing rate, which is the rate incurred to borrow on a collateralized basis over a similar term an amount equal to the lease payments in a similar economic environment. As of January 1, 2022, the ASC 842 effective date, the Company's incremental borrowing rate was approximately 6.5% based on the remaining lease term of the applicable leases.

The Company has elected to combine lease and non-lease components as a single component. Operating leases are recognized on the balance sheet as ROU lease assets, lease liabilities current and lease liabilities non-current. Fixed rents are included in the calculation of the lease balances while variable costs paid for certain operating and pass-through costs are excluded. Lease expense is recognized over the expected term on a straight-line basis.

Convertible Preference Shares

We classified convertible preference shares outside of stockholders' equity on our balance sheet as certain liquidation events are not strictly within our control. We recorded the issuance of convertible preference shares at the issuance price less related issuance costs.

Equity-Based Compensation

We account for stock options granted in accordance with ASC 718, *Compensation-Stock Compensation*. In accordance with ASC 718, compensation expense is measured at the estimated fair value of the stock options at grant date and is included as compensation expense over the vesting period during which an employee provides service in exchange for the award. award on a straight-line basis. Vesting of the awards depend solely on service conditions required of the employee.

All share-based awards granted are measured based on the fair value on the date of the grant and compensation expense is recognized with respect to those awards over the requisite service period, which is generally the vesting period of the respective award. The Company reverses any previously recognized compensation cost associated with forfeited awards in the period the forfeiture occurs.

Equity-based compensation expense is classified in the Company's consolidated statements of operations and comprehensive loss in the same manner in which the award recipients' payroll costs are classified or in which the award recipients' service payments are classified. The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes model. The following summarizes the inputs used:

Expected volatility: The Company estimates its expected stock volatility based on the historical volatility of a publicly traded set of peer companies because we lack company-specific historical and implied volatility information due in part to the limited time in which we have operated as a publicly traded company. We expect to continue to do so until such time as we have adequate historical data regarding the volatility of our traded stock price.

Expected term: The expected term of the Company's stock options has been determined based on the expected time to liquidity. The Company uses the simplified method prescribed by the SEC's Staff Accounting Bulletin No. 107, Share-Based

Payment, to calculate the expected term of options granted because we lack company-specific historical and implied expected term information due in part to the limited time in which we have operated as a publicly traded company.

Risk-free interest rate: The risk-free interest rate is based on the implied yield on a U.S. Treasury security at a constant maturity with a remaining term equal to the expected term of the option granted.

Dividends: Expected dividend yield is zero because the Company does not pay cash dividends on common shares and does not expect to pay any cash dividends in the foreseeable future.

Prior Share Price: The Company's common stock trades on the Nasdaq Global Market under the symbol "IOBT" and is utilized to determine the fair value of the Company's IPO, valuations were updated when facts and circumstances indicated that the most recent valuation was no longer valid, including as a result of changes in the stage of development efforts, various exit strategies and their timing, and other scientific developments that could be related to the Company's valuation, or, at a minimum, annually. Third-party valuations were performed in accordance with the guidance outlined in the American Institute of Certified Public Accountants' Accounting and Valuation Guide, Valuation of Privately-Held-Company Equity Securities Issued as Compensation. share price.

Income Taxes

Deferred income tax assets and liabilities arise from temporary differences associated with differences between the financial statements and tax basis of assets and liabilities, as measured by the enacted tax rates, which are expected to be in effect when these differences reverse. Deferred tax assets and liabilities are classified as current or non-current, depending upon the classification of the asset or liabilities to which they relate. Deferred tax assets and liabilities not related to an asset or liability are classified as current or non-current depending on the periods in which the temporary differences are expected to reverse. Valuation allowances are established when necessary, to reduce deferred tax assets to the amount expected to be realized.

We follow the provisions of ASC 740-10, *Uncertainty in Income Taxes.* We have not recognized a liability as a result of ASC 740-10. A reconciliation of the beginning and ending amount of unrecognized tax benefits has not been provided since there is no unrecognized benefit since the date of adoption and we have not recognized interest expense or penalties as a result of ASC 740-10. If there were an unrecognized tax benefit, we would recognize interest accrued related to unrecognized tax benefits in interest as income tax expense and penalties in operating expenses.within our consolidated statements of operations.

We have identified Denmark and the U.S. as our major tax jurisdictions.

Warrants Issued in Connection with Sale of Common Stock

The Company accounts for warrants issued as a separable unit in connection with sale of common stock as either liability or equity in accordance with ASC 480-10, Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity ("ASC 480-10") or ASC 815-40, Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock ("ASC 815-40"). Under ASC 480-10, warrants are considered liabilities if they are mandatorily redeemable and they require settlement in cash or other assets, or a variable number of shares. If warrants do not meet liability classification under ASC 480-10, the Company considers the requirements of ASC 815-40 to determine whether the warrants should be classified as liability or equity. If warrants do not require liability classification under ASC 815-40 or other applicable U.S. GAAP the warrants should be classified as equity.

The proceeds received from the sale of equity classified warrants and shares of common stock in a bundled transaction are allocated based on the relative fair values of warrants and shares of common stock with no changes in fair value of warrants recognized after the issuance date. Based on our analysis of the foregoing, the Company's warrants issued in the Private Placement are classified as equity in our consolidated financial statements.

Net Loss Per Share

We calculate basic and dilutedBasic net loss per share attributable to ordinary shareholders in conformity with the two-class method required for participating securities. Our convertible preference shares were participating securities in Company distributions. The net loss attributable to ordinary shareholders is not allocated to the convertible preference shares as the holders of convertible preference shares do not have a contractual obligation to share in losses. Cumulative dividends on preference shares are added to net loss to arrive at net loss available to ordinary shareholders.

Under the two-class method, basic net loss per share attributable to ordinary shareholders is computed by dividing the net loss attributable to ordinary common shareholders by the weighted averageweighted-average number of ordinary shares of common stock outstanding duringfor the period, without consideration of potential dilutive securities. period. Diluted net loss per share is calculated computed by dividing the net loss attributable to common shareholders by the weighted averageweighted-average number of shares of ordinary shares common stock and potential dilutive common share stock equivalents outstanding duringfor the period, determined using the treasury-stock method and the as if-converted method, for convertible securities, if the effect inclusion of these instruments is dilutive. Potentially dilutive securities include stock options and warrants to purchase common stock of the Company. In all periods presented, the Company's outstanding stock options and warrants were excluded from the calculation of diluted net loss per share because their effects were anti-dilutive.

For the years ended December 31, 2023 and 2022, both basic and diluted net loss per share are equivalent.

Segments

Operating segments are defined as components of an entity for which separate financial information is available and that is regularly reviewed by the chief operating decision maker (CODM), in deciding how to allocate resources to an individual segment and in assessing performance. Our CODM is our chief executive officer. We have determined we operate in The Company has concluded it has a single segment.reporting segment for purposes of reporting financial condition and results of operations.

Other Comprehensive Income (Loss)

OCI 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. Our OCI includes currency translation from the Euro and the British Pound, the functional currency of IO Biotech ApS and IO Biotech Limited, respectively, to the U.S. Dollar, our reporting currency.

Emerging Growth Company Status

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act (JOBS Act). Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act, until such time as those standards apply to private companies. We have elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date that we (1) are no longer an emerging growth company or (2) affirmatively and irrevocably opts out of the extended transition period provided in the JOBS Act. As a result, these financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates.

Recently Issued Accounting Standardsadopted accounting standards

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments-Credit Instruments—Credit Losses: Measurement of Credit Losses on Financial Instruments.* Instruments. ASU 2016-13 requires measurement and recognition ofexpected credit losses for financial assets. In April 2019, the FASB issued clarification to ASU 2016-13 withinASU 2019-04, Codification Improvements *to Topic 326, Financial Instruments-Credit Instruments—Credit Losses, Topic 815, Derivatives and Hedging,, and Topic 825, Financial Instruments,*. or ASU 2016-13. The guidance is effective for fiscal yearsbeginning after December 15, 2022. The Company is assessing the potential impact of adopting ASU has adopted2016-13 on our financial statements and financial statement disclosures and does not currently expect a material impact on our financial statements or financial statement disclosures upon adoption.

In December 2019, the FASB issued ASU 2019-12, *Simplifying the Accounting for Income Taxes*. ASU 2019-12 eliminates certain exceptions related to the approach for intra-period tax allocation, the methodology for calculating income taxes in an interim period and the recognition of deferred tax liabilities for outside basis differences. It also clarifies and simplifies other aspects of the accounting for income taxes. The Company has adopted the standard effective for fiscal year December 31, 2022January 1, 2023. The adoption of the standard has notnot had a material impact on our financial statements or financial statement disclosures.

Recently Issued Accounting Standards

In August 2020, the FASB issued ASU No. 2020-06, *Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging Contracts in Entity s Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity*. ASU 2020-06 will simplify the accounting for convertible instruments by reducing the number of accounting models for convertible debt instruments and convertible preferred stock. Limiting the accounting models results in fewer embedded conversion features being separately recognized from the host contract as compared with current U.S. GAAP. Convertible instruments that continue to be subject to separation models are (1) those with embedded conversion features that are not clearly and closely related to the host contract, that meet the definition of a derivative, and that do not qualify for a scope exception from derivative accounting and (2) convertible debt instruments issued with substantial premiums for which the premiums are recorded as paid-in capital. ASU 2020-06 also amends the guidance for the derivatives scope exception for contracts in an entity's own equity to reduce form-over-substance-based accounting conclusions. ASU 2020-06 will be effective for us in the interim periods in the fiscal year beginning after December 15, 2023. Early adoption is permitted, but no earlier than fiscal years beginning after December 15, 2020, including interim periods within those fiscal years. We are currently assessing the impact adoption of ASU 2020-06 will have on our financial statements and disclosures, but do not expect a material impact on the financial statements or disclosures.

In October 2023, the FASB issued ASU 2023-06, Accounting Standards Update 2023-06—Disclosure Improvements: Codification Amendments in Response to the SEC's Disclosure Update and Simplification Initiative. ASU 2023-06 will eliminate disclosure requirements that are redundant, duplicative, overlapping, outdated, or superseded as a result of subsequent changes to SEC disclosure requirements, U.S GAAP or technology. ASU 2023-06 is intended to better align U.S. GAAP requirements with those of the SEC and to facilitate the application of U.S. GAAP. The disclosure requirements would apply prospectively in the financial statements. ASU 2023-06 will be effective for us on the date on which the SEC's removal of that related disclosure requirement from Regulation S-X or Regulation S-K becomes effective, if we are already subject to the SEC's current disclosure requirements. For those current disclosure requirements we are not subject to, ASU 2023-06 will become effective two years after the date of such removal by the SEC. We are currently assessing the impact adoption of ASU 2023-06 will have on our financial statements and disclosures.

In November 2023, the FASB issued ASU 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures. ASU 2023-07 will improve reportable segment disclosure requirements, primarily through enhanced disclosures about significant segment expenses. ASU 2023-07 will also enhance interim disclosure requirements, clarify circumstances in which an entity can disclose multiple segment measures of profit or loss, provide new segment disclosure requirements for entities with a single reportable segment and contain other disclosure requirements. The enhanced segment disclosure requirements apply retrospectively to all prior periods presented in the financial statements. ASU 2023-07 will be effective for us in the annual periods beginning after December 15, 2023. We are currently assessing the impact adoption of ASU 2023-07 will have on our financial statements and disclosures, but do not expect a material impact on the financial statements or disclosures.

In December 2023, the FASB issued ASU 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures. ASU 2023-09 will require disclosure of additional information in specified categories with respect to the reconciliation of the effective tax rate to the statutory rate (the rate reconciliation) for federal, state and foreign income taxes. ASU 2023-09 will also require information pertaining to taxes paid (net of refunds received) to be disaggregated for federal, state and foreign taxes and further disaggregated for specific jurisdictions to the extent the related amounts exceed a quantitative threshold. ASU 2023-09 will be effective for us in the annual periods beginning after December 15, 2025. Early adoption is permitted for annual financial statements that have not yet been issued or made available for issuance. We are currently assessing the impact adoption of ASU 2020-06 will have on our financial statements and disclosures.

Other than the items noted above, there have been no new accounting pronouncements not yet effective or adopted in the current year that we believe have a significant impact, or potential significant impact, to our consolidated financial statements. statements.

3. Fair Value Measurements

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on

the measurement date. Valuation techniques used to measure fair value are performed in a manner to maximize the use of observable inputs and minimize the use of unobservable inputs.

The Company classified its money market funds within Level 1 as the fair value of the funds are based on their quoted market prices in an active market.

The following tables present information about our financial assets and liabilities measured at fair value on a recurring basis and indicate the level of the fair value hierarchy utilized to determine such fair values as of December 31, 2022 December 31, 2023 and 2021 2022 (in thousands):

	December 31, 2022				December 31, 2023			
	Total	Level 1	Level 2	Level 3	Total	Level 1	Level 2	Level 3
Assets								
Money market funds(1)	$ 87,971	$ 87,971	$ —	$ —	$ 131,613	$ 131,613	$ —	$ —
Total assets measured at fair value	$ 87,971	$ 87,971	$ —	$ —	$ 131,613	$ 131,613	$ —	$ —

	December 31, 2021				December 31, 2022			
	Total	Level 1	Level 2	Level 3	Total	Level 1	Level 2	Level 3
Assets								
Money market funds(1)	$ 101,561	$ 101,561	$ —	$ —	$ 87,971	$ 87,971	$ —	$ —
Total assets measured at fair value	$ 101,561	$ 101,561	$ —	$ —	$ 87,971	$ 87,971	$ —	$ —

(1) Money market funds with maturities of 90 days or less at the date of purchase are included within cash and cash equivalents in the accompanying consolidated balance sheets and are recognized at fair value.

The following table presents a roll-forward of the fair value of the convertible note and preference shares tranche obligations for which fair value is determined by Level 3 inputs (in thousands):

	Preference Shares Tranche Obligations
Balance, December 31, 2020	—
Addition on issuance of Class C preference shares	2,425
Fair value adjustments	26,830
Currency exchange	(979)

Settlement of preference shares tranche obligation through issuance of preference shares	(28,276)
Balance, December 31, 2021	$ —

Valuation techniques used to measure fair value maximize the use of relevant observable inputs and minimize the use of unobservable inputs. Our convertible notes and preference shares tranche obligations, which were issued and settled during the year ended December 31, 2021, were classified within Level 3 of the fair value hierarchy because the fair value measurement was based, in part, on significant inputs not observed in the market. As of December 31, 2022 December 31, 2023 and 2021, 2022, the Company only held Level 1 financial instruments, respectively.

Our Class C Preference Shares Tranche Obligation was measured at fair value using a Black-Scholes option pricing valuation methodology. The fair value of Class C Preference Shares Tranche Obligation included inputs not observable in the market and thus represents a Level 3 measurement. The option pricing valuation methodology utilized required inputs based on certain subjective assumptions, including (1) expected stock price volatility; (2) calculation of an expected term; (3) a risk-free interest rate; and (4) expected dividends. The assumptions utilized to value the class C Preference Shares Tranche Obligation during 2021 were (1) expected stock price volatility of 73.7%; (2) remaining term of 0.3 years; (3) a risk-free interest rate of 0.05%; and (4) an expectation of no dividends.instruments.

There were no transfers among Level 1, Level 2 or Level 3 categories in the years ended December 31, 2022 23 and 2021, 22.

4. License and Collaboration Agreements

Clinical Trial Collaboration and Supply Agreements with MSD International GmbH

In February 2018, we entered into a clinical collaboration with MSD International GmbH (MSDIG), to evaluate IO102 in combination with KEYTRUDA®KEYTRUDA® (pembrolizumab) in first-line treatment of patients with metastatic non-small cell lung cancer. Under the terms of the collaboration with MSDIG, we will conduct an international Phase 1/2 study to evaluate a

combination therapy of IO102 and KEYTRUDA®KEYTRUDA®. We will sponsor the clinical trials and MSDIG will provide KEYTRUDA®KEYTRUDA® to be used in the clinical trials free of charge. We and MSDIG will be responsible for our own internal costs and expenses to support the study and we shall bear all other costs associated with conducting the study, including costs of providing IO102 for use in the study. The rights to the data from the clinical trials will be shared by us and MSDIG and we will maintain global commercial rights to IO102.

In September 2021, we entered into a clinical collaboration with MSDIG and MSD International Business GmbH (MSDIB), another affiliate of Merck (collectively, "MSD") to evaluate IO102-IO103 in combination with KEYTRUDA®KEYTRUDA® versus KEYTRUDA® KEYTRUDA® alone in treatment of patients with metastatic (advanced) melanoma. Under the terms of the collaboration with MSD, we will conduct are conducting an international Phase 3 study to evaluate a combination therapy of IO102-IO103 and KEYTRUDA KEYTRUDA®. We are the sponsor of the clinical trials and MSD will provide KEYTRUDA® to be used in the clinical trials free of charge. We and MSD are responsible for our own internal costs and expenses to support the study and we will bear all other costs associated with conducting the study, including costs of providing IO102-IO103 for use in the study. The rights to the data from the clinical trials will be shared by us and MSD and we will maintain global commercial rights to IO102-IO103.

® In December 2021, we entered into a clinical collaboration with MSD to evaluate IO102-IO103 in combination with KEYTRUDA® in previously untreated patients with three different tumor types— metastatic non-small cell lung cancer (NSCLC), squamous cell carcinoma of the head and neck (SCCHN), and urothelial bladder cancer (UBC). Under the terms of the collaboration with MSD, we are conducting an international Phase 2 study to evaluate a combination therapy of IO102-IO103 and KEYTRUDA®. We are the sponsor of the clinical trials and MSD will provide KEYTRUDA® to be used in the clinical trials free of charge. We and MSD are responsible for our own internal costs and expenses to support the study and we will bear all other costs associated with conducting the study, including costs of providing IO102-IO103 for use in the study. The rights to the data from the clinical trials will be shared by us and MSD and we will maintain global commercial rights to IO102-IO103.

In November 2022, we entered into a clinical collaboration with MSD to evaluate IO102-IO103 in combination with KEYTRUDA® as a neo-adjuvant/adjuvant therapy for patients with metastatic melanoma and SCCHN. Under the terms of the collaboration with MSD, we will conduct an international Phase 2 study to evaluate a combination therapy of IO102-IO103 and KEYTRUDA®. We will sponsor the clinical trials and MSD will provide KEYTRUDA®KEYTRUDA® to be used in the clinical trials free of charge. We and MSD will be responsible for our own internal costs and expenses to support the study and we shall bear all other costs associated with conducting the study, including costs of providing IO102-IO103 for use in the study. The rights to the data from the clinical trials will be shared by us and MSD and we will maintain global commercial rights to IO102-IO103.

In December 2021, we entered into a clinical collaboration with MSD to evaluate IO102-IO103 in combination with KEYTRUDA® in previously untreated patients with three different tumor types— metastatic NSCLC, SCCHN, and UBC. Under the terms of the collaboration with MSD, we will conduct an international Phase 2 study to evaluate a combination therapy of IO102-IO103 and KEYTRUDA®. We will sponsor the clinical trials and MSD will provide KEYTRUDA® to be used in the clinical trials free of charge. We and

MSD will be responsible for our own internal costs and expenses to support the study and we shall bear all other costs associated with conducting the study, including costs of providing IO102-IO103 for use in the study. The rights to the data from the clinical trials will be shared by us and MSD and we will maintain global commercial rights to IO102-IO103.

In November 2022, we entered into a clinical collaboration with MSD to evaluate IO102-IO103 in combination with KEYTRUDA® as a neo-adjuvant/adjuvant therapy for patients with metastatic melanoma and SSCHN. Under the terms of the collaboration with MSD, we will conduct an international Phase 2 study to evaluate a combination therapy of IO102-IO103 and KEYTRUDA®. We will sponsor the clinical trials and MSD will provide KEYTRUDA® to be used in the clinical trials free of charge. We and MSD will be responsible for our own internal costs and expenses to support the study and we shall bear all other costs associated with conducting the study, including costs of providing IO102-IO103 for use in the study. The rights to the data from the clinical trials will be shared by us and MSD and we will maintain global commercial rights to IO102-IO103.

Agreements with Herlev Hospital

The Company has a number of existing agreements with the Herlev University Hospital in Denmark (Herlev) for scientific and other support of our ongoing development activities. In January 2021, the Company entered into an additional agreement with Herlev regarding the payment of specific services whereupon in addition to any consideration payable by the Company to Herlev pursuant to the existing agreements we were required to pay a fee to Herlev of DKK 5.0 million (approximately $0.8 million) in the event of an initial public offering or other liquidity event whereby all or substantially all of the value of the Company is realized in consideration for cash. The Company consummated its IPO in November 2021, resulting in this payment to Herlev becoming payable. Additionally, upon the completion of the IPO, the Company was obligated to make payments to Herlev in the aggregate amount of DKK 13.2 million, (which is approximately $2.1 million based on the exchange rate of DKK 6.54 to one U.S. Dollar on December 31, 2021). In total, the Company accrued for and expensed $2.9 million in consideration payable to Herlev Hospital in accordance with existing agreements. The $2.9 million was expensed to research and development expense for the year ended December 31, 2021 and was subsequently paid in February 2022.

5. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist of the following (in thousands):

	December 31,		December 31,	
	2022	2021	2023	2022
Prepaid contract research and development costs	$ 1,695	$ 4,770		
Insurance	1,716	3,197	$ 1,352	$ 1,716
Research and development tax credit receivable	792	841	814	792
Prepaid income taxes			829	124
Value-added tax refund receivable	741	1,250	313	741
Prepaid contract research and development costs			—	1,695
Other	685	149	754	561
Total prepaid expenses and other current assets	$ 5,629	$ 10,207	$ 4,062	$ 5,629

6. Property and Equipment, Net

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

	December 31,		December 31,	
	2022	2021	2023	2022
Laboratory equipment	$ 544	$ 68	$ 836	$ 544
Office furniture			238	233
Computer hardware	79	35	103	79
Office furniture	233	64		
Less: accumulated depreciation	(115)	(12)	(330)	(115)

Total Property and Equipment, net	$ 741	$ 155		
Total property and equipment, net			$ 847	$ 741

For the years ended December 31, 2022 December 31, 2023 and 2021, 2022, the Company recognized $0.1 0.2 million and $0.0 0.1 million, respectively, of depreciation expense in the consolidated statements of operations.

7. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consist of the following (in thousands):

	December 31,		December 31,	
	2022	2021	2023	2022
Accrued contract research and development costs	$ 1,936	$ 3,861	$ 6,153	$ 1,936
Employee compensation costs			4,225	1,863
Professional fees	407	1,028	243	407
Employee compensation costs	1,863	1,027		
Other liabilities	1,951	461	563	1,951
Total accrued expenses and other current liabilities	$ 6,157	$ 6,377	$ 11,184	$ 6,157

8. Leases

On January 1, 2022, the Company adopted ASC 842 using the modified retrospective transition approach allowed under ASU 2018-11 which releases companies from presenting comparative periods and related disclosures under ASC 842 and requires a cumulative-effect adjustment to the opening balance of accumulated deficit in the period of adoption (Note 2). The Company had an immaterial cumulative-effect adjustment to the opening balance of accumulated deficit as of January 1, 2022. The Company is party to three five operating leases for laboratory and office space. The Company's finance leases are immaterial both individually and in the aggregate. The Company has elected to apply the short-term lease exception to all leases of one year or less. As of December 31, 2022, this exception applied to one operating lease for office and laboratory space in Denmark that expired on December 31, 2022 and another operating lease for office space in the UK that is payable month to month. Further, the Company has applied the guidance in ASC 842 to our corporate office and laboratory leases and has determined that these should be classified as operating leases. Consequently, as a result of the adoption of ASC 842 on January 1, 2022, we recognized an ROU lease asset of approximately $2.3 million with a corresponding lease liability of approximately $2.4 million based on the present value of the minimum rental payments of such leases. In accordance with ASC 842, the beginning balance of the ROU lease asset was reduced by the existing deferred rent liability at inception of approximately $0.1 million. In the consolidated balance sheet as of December 31, 2022 December 31, 2023, the Company has an ROU asset balance of $2.5 2.3 million and a

current and non-current lease liability of $0.5 0.7 million and $2.3 1.8 million, respectively, relating to the ROU lease asset. The balance of both the ROU lease asset and the lease liabilities primarily consists of future payments under the Company's office leased in New York, New York, Rockville, Maryland and Copenhagen, Denmark.

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The Company is party to an operating lease in Copenhagen, Denmark for office and laboratory space that commenced in March 2021 with the an initial term set to expire that expired in January 2025. Base rent for this initial lease was approximately $0.1 million annually. The Company amended its operating lease in Copenhagen, Denmark on September 1, 2022 with a new term set to expire in December 2027. The base rent for the amended lease is approximately $0.2 million annually. The Company is also party to an operating lease in Copenhagen, Denmark for laboratory space that commenced in January 2023 with the term set to expire in December 2027. The base rent for the lease is $0.04 million annually. The Company is party to an operating lease in New York, New York for office and laboratory space that commenced in October 2021 with the initial term set to expire in January 2027. Base rent for this lease is approximately $0.2 million annually. The Company is party to an operating lease in Rockville, Maryland for office and laboratory space that commenced in December 2021 with the initial term set to expire in May 2027. Base rent for this lease is approximately $0.3 million annually. The Company is party to an immaterial operating lease in Newport, United Kingdom that commenced in June 2023. Rent expense for the years ended December 31, 2022 December 31, 2023 and 2021 2022 was $0.8 0.7 million and $0.3 0.8 million, respectively.

Quantitative information regarding the Company's leases for the year ended December 31, 2022 December 31, 2023 is as follows (in thousands):

Lease Cost	Year ended December 31, 2022	Year Ended December 31, 2023	Year Ended December 31, 2022
Operating lease cost	$ 755	$ 730	$ 755
Operating cash flows paid for amounts included in the measurement of lease liabilities	$ 419	$ 723	$ 419
Operating lease liabilities arising from obtaining right-of-use assets	$ 2,600	$ 235	$ 2,600
Remaining lease term (years)	4.47	3.5	4.5
Weighted average discount rate	6.5 %	6.3 %	6.5 %

Future lease payments (undiscounted) under noncancelable leases are as follows as of December 31, 2022 December 31, 2023 (in thousands):

Future Lease Payments	Amount	Amount
2023	$ 678	
2024	711	$ 793
2025	731	792
2026	751	798
2027	354	403
2028		—
Thereafter	—	—
Total	$ 3,225	$ 2,786

The Company's leases do not provide an implicit rate, therefore the Company used its incremental borrowing rate based on the information available at commencement date in determining the present value of lease payments. The Company used the incremental borrowing rate on January 1, 2022 for operating leases that commenced prior to that date, which is the rate incurred to borrow on a collateralized basis over a similar term an amount equal to the lease payments in a similar economic environment.

9. Commitments and Contingencies

From time to time, we may be party to litigation arising in the ordinary course of its business. We were not subject to any material legal proceedings during the years ended December 31, 2022 December 31, 2023 and 2021, 2022, and, to our knowledge, no material legal proceedings are currently pending or threatened.

Contractual Obligations and Commitments

We enter into contracts in the ordinary course of business with third-party service providers for clinical trials, preclinical research studies and testing, manufacturing and other services and products for operating purposes. These contracts generally provide for termination upon notice of 30 to 90 days, days, and therefore, we believe that our non-cancelable noncancelable obligations under these agreements are not material and we cannot reasonably estimate whether they will occur. However, in the event of a termination of any contracts with CROs or other institutions and with respect to active patients enrolled in our clinical trials, we may be financially obligated for a period beyond the contractual termination notice periods. We may also enter into additional research,

manufacturing, supplier, lease and other agreements in the future, which may require up-front payments and even long-term commitments of cash.

Indemnification Agreements

We enter into certain types of contracts that contingently requires us to indemnify various parties against claims from third parties. These contracts primarily relate to procurement, service, consultancy or license agreements under which we may be required to indemnify vendors, service providers or licensees for certain claims, including claims that may be brought against them arising from our acts or omissions with respect to our products, technology, intellectual property or services. The Company, as permitted under

Delaware law and in accordance with its amended and restated certification certificate of incorporation and amended and restated bylaws and pursuant to indemnification agreements with certain of its officers and directors, indemnifies its officers and directors for certain events or occurrences, subject to certain limits, which the officer or director is or was serving at the Company's request in such capacity. At the 2023 Annual Meeting of Stockholders, the Company's stockholders approved an amendment to, and the Company subsequently amended, its amended and restated certificate of incorporation to extend the indemnification of officers pursuant to recent amendments to the General Corporation Law of the State of Delaware.

From time to time, we may receive indemnification claims under these existing contracts in the normal course of business. In the event that one or more of these matters were to result in a claim against us, an adverse outcome, including a judgment or settlement, may cause a material adverse effect on our future business, operating results or financial condition. It is not possible to estimate the maximum amount potentially payable under these contracts since we have no history of prior indemnification claims and the unique facts and circumstances involved in each particular claim will be determinative.

10. Convertible Preference Shares

As of December 31, 2022 and 2021, we had no preference shares authorized, issued and outstanding.

Sales and Issuances of Preference Shares During the Years Ended December 31, 2022 and 2021

In January 2021, we completed an investment agreement, Class C Investment Agreement, for the sale and issuance of up to 1,263,804 Class C preference shares to new investors and existing related-party investors at a subscription price of $121.55 per share. Then, pursuant to the Class C Investment Agreement, we issued 505,520 Class C preference shares for gross cash proceeds of $61.5 million. The Class C Investment Agreement further provided for a milestone closing in the event of certain development milestones before April 2022, whereby purchasers of Class C preference shares are obligated to a further subscription amount of $88.4 million, or the Preference Shares Tranche Obligation, which resulted in a further issuance of 689,344 Class C preference shares at a subscription price of $128.19 per share. We incurred issuance costs of $0.3 million in connection with the issuances of the Class C preference shares.

We concluded that the Preference Shares Tranche Obligation met the definition of a freestanding financial instrument, as it was legally detachable and separately exercisable from the class C preference shares. Therefore, we allocated the proceeds received from the issuance of shares under the Class C Investment Agreement between the Preference Shares Tranche Obligation and the Class C preference shares. The fair value of the Preference Shares Tranche Obligation of $2.4 million on issuance was allocated from the $61.5 million proceeds of the Class C preference shares financing and was classified as a current liability on the balance sheet as the Class C preference shares would become redeemable upon a Deemed Liquidation Event, the occurrence of which is not within our control.

In March 2021, prior to a milestone closing, an investor elected to purchase and we issued 35,825 Class C preference shares for gross cash proceeds of $4.2 million pursuant to the Class C Investment Agreement. As a result of entering into a collaboration agreement with Merck in September 2021, the number of Class C preference shares issued in March 2021 was adjusted downward to 32,568 Class C preference shares. In October 2021, investors purchased and we issued 656,776 Class C preference shares for gross cash proceeds of $84.1 million pursuant to the Class C Investment Agreement, resulting in the settlement of the preference shares tranche obligations.

Immediately prior to consummation of our IPO, all outstanding Class B and Class C preference shares were converted into 20,415,213 shares of common stock.

11. Stockholders' Equity

Common and Preferred Stock

In November 2021, we completed our IPO selling an aggregate of 8,222,500 shares of common stock at $14.00 per share, which included 1,072,500 shares that represented the full exercise of an option to purchase additional shares granted to the underwriters in connection with the IPO. The offering resulted in $103.3 million of net proceeds to us, after deducting

underwriting discounts and commissions and other offering expenses. Upon the closing of our IPO in November 2021, we filed an amended and restated certificate of incorporation, which authorized us to issue 300,000,000 shares of common stock and 5,000,000 shares of preferred stock. The shares of preferred stock are currently undesignated. Common stockholders are entitled to one vote for each share of common stock held at all meetings of stockholders and written actions in lieu of meetings. Common stockholders are entitled to receive dividends, if and when declared by the Company's board of directors (Board). No dividends have been declared or paid by us through December 31, 2022 December 31, 2023.

The Private Placement

On August 7, 2023, the Company entered into the Purchase Agreement, pursuant to which the Company agreed to sell and issue (i) 37,065,647 shares of the Company's common stock, and (ii) 37,065,647 Warrants in the Private Placement. Each Purchaser's Warrant is exercisable for a number of shares of common stock equal to one hundred percent of the aggregate number of shares of common stock purchased by such Purchaser. The Purchase Price for each common stock and Warrant was $2.025 per share.

The Warrants are exercisable at an exercise price of $2.47 per share, subject to adjustment as set forth therein. The Warrants are exercisable until the earlier of (i) February 9, 2027, and (ii) one day prior to the closing of an acquisition, as defined in the Warrants. The Warrants may be exercised on a cashless basis if there is no effective registration statement registering the shares underlying the Warrants.

The Private Placement closed on August 9, 2023. The Company received $75.1 million in gross proceeds from the Private Placement, before deducting offering expenses of $3.2 million. Of the total proceeds, legal entities of certain related parties contributed $33.4 million, and members of management contributed $0.2 million. The Company intends to use the net proceeds of $71.9 from the Private Placement for general corporate purposes.

The Warrants were classified as a component of permanent stockholders' equity within additional paid-in-capital and were recorded at the issuance date using a relative fair value allocation method. The Warrants are equity classified because they are freestanding financial instruments that are legally detachable and separately exercisable from the equity instruments, are immediately exercisable, do not embody an obligation for the Company to repurchase its shares, permit the holders to receive a fixed number of common shares upon exercise, are indexed to the Company's common stock and meet the equity classification criteria. In addition, such Warrants do not provide any guarantee of value or return. The Company valued the Warrants at issuance using the Black-Scholes valuation model and allocated proceeds from the sale proportionately to the common stock and Warrants, of which $29.6 million was allocated to the Warrants and recorded as a component of additional paid-in-capital. As of December 31, 2023, the Company had 37,065,647 warrants issued and outstanding at an exercise price of $2.47 per share to purchase shares of the Company's common stock.

In connection with the execution of the Purchase Agreement, the Company also entered into a registration rights agreement (the Registration Rights Agreement) with the Purchasers. Under the terms of the Registration Rights Agreement, the Company has filed the Registration Statement with the SEC to register for resale the common stock issued under the Purchase Agreement and the shares of common stock issuable upon conversion of the Warrants issued pursuant to the Purchase Agreement (the Registrable Securities), which Registration Statement was declared effective on September 8, 2023. The Company may be required to pay certain liquidated damages under the terms of the Registration Rights Agreement in the event sales cannot be made pursuant to the Registration Statement.

As of December 31, 2022 December 31, 2023 and 2021, 2022, the Company had65,880,914 and 28,815,267 common shares outstanding, respectively.

12. 11. Equity-Based Compensation

Employee 2021 Equity Incentive Plan

Prior to our IPO, we issued warrants to certain employees, board members and advisors (Pre-IPO Plan). Each vested warrant entitled the warrant holder to a single class A ordinary share. Holders of stock warrants were entitled to exercise the vested portion of the stock warrant. Stock warrants generally vest over a three-year period and expire five years from the vest date.

In November 2021, our Board adopted, and our stockholders approved, the 2021 Equity Incentive Plan (2021 Equity Plan), which became effective on November 4, 2021. The 2021 Equity Plan provides for the grant of incentive stock options, non-statutory stock options, stock appreciation rights, awards of restricted stock, restricted stock units and other stock-based awards. The number of shares of our common stock reserved for issuance under the 2021 Equity Plan is equal to 2,465,150 2,496,934, subject to an annual increase, to be added on the first day of each fiscal year, beginning with the fiscal year ending December 31, 2022 and continuing until, and including, the fiscal year ending December 31, 2031, equal to the lesser of (1) (i) 4% of the number of shares of common stock outstanding on the first day of such fiscal year or (2) (ii) such other amount determined by our Board. The 2,396,413 outstanding warrants granted under the Pre-IPO Plan were transferred to the 2021 Equity Plan and no further warrants were available to be issued under the Pre-IPO Plan. As of December 31, 2022 December 31, 2023, we had 1,389,248 593,468 options available for future grant under the 2021 Equity Plan.

The following table summarizes our stock options activity for the years ended December 31, 2022 and 2021:

	Number of Options and Warrants	Weighted-average exercise price per share	Weighted-average remaining contractual term (in years)	Aggregate intrinsic value (in thousands)
Outstanding December 31, 2020	89,935	$ 15.00	4.6	$ —
Granted	2,981,678	$ 14.58	—	$ —
Outstanding December 31, 2021	3,071,613	$ 13.12	8.5	$ —
Granted	1,211,155	$ 5.34	—	$ —
Cancelled or forfeited	(362,596)	$ 12.51	—	$ —
Outstanding, December 31, 2022	3,920,172	$ 10.77	8.1	$ —
Exercisable at December 31, 2022	993,841	$ 13.04	7.3	$ —

2021 Employee Stock Purchase Plan

In November 2021, our board of directors Board adopted and our stockholders approved the 2021 IO Biotech, Inc. Employee Stock Purchase Plan (2021 ESPP), which became effective on November 4, 2021. The number of shares of our common stock reserved for issuance under the 2021 ESPP is equal to 257,272, subject to an annual increase, to be added on the first day of each fiscal year, beginning January 1, 2023, equal to the lesser of (1) 1% of the number of shares of common stock outstanding on the first day of such fiscal year; (2) 257,272 shares of our common stock; or (3) such other amount as determined by our board of directors. Board. As of December 31, 2022 December 31, 2023, the Board had not yet approved any offering under the 2021 ESPP.

Equity-Based Compensation2023 Inducement Award Plan

In October 2021, September 2023, our Board approved adopted the amendment 2023 Inducement Award Plan (2023 Inducement Plan), which became effective on September 28, 2023. The 2023 Inducement Plan provides for the grant of all nonvested warrant non-statutory stock options, stock appreciation rights, awards issued in July of restricted stock, restricted stock units and August 2021 with an exercise price other stock-based awards to eligible employees who satisfy the standards for inducement grants under Nasdaq Global Market rules. The number of $19.62 per share to reduce the exercise price of such warrants to $12.64 per share. Warrants to purchase an aggregate of 670,849 shares of our Class A ordinary common stock reserved for issuance under the 2023 Inducement Plan is equal to 1,976,427. As of December 31, 2023, there were 1,976,427 shares were modified. available for future grant under the 2023 Inducement Plan.

The vesting schedule of such awards was not modified. The modification resulted in a $0.6 million charge which will be recognized over following table summarizes our stock options activity for the remaining vesting periods of each award averaging 3.75 years. years ended December 31, 2023 and 2022:

	Number of Options and Warrants	Weighted-average exercise price per share	Weighted-average remaining contractual term (in years)	Aggregate intrinsic value (in thousands)
Outstanding December 31, 2021	3,071,613	$ 13.12	8.5	$ —
Granted	1,211,155	$ 5.34	—	$ —
Cancelled or forfeited	(362,596)	$ 12.51	—	$ —
Outstanding December 31, 2022	3,920,172	$ 10.77	8.1	$ —
Granted	2,519,994	$ 1.99	—	$ —
Cancelled or forfeited	(588,243)	$ 8.74	—	$ —
Outstanding, December 31, 2023	5,851,923	$ 7.20	8.4	$ 102
Exercisable at December 31, 2023	1,902,547	$ 11.26	7.7	$ 2

Equity-Based Compensation

All share-based awards granted are measured based on the fair value on the date of the grant and compensation expense is recognized with respect to those awards over the requisite service period, which is generally the vesting period of the respective award. Forfeitures related to equity-based compensation awards are recognized as they occur, and we reverse any previously recognized compensation cost associated with forfeited awards in the period the forfeiture occurs.

For the years ended December 31, 2022 December 31, 2023 and 2021, 2022, we recorded equity-based compensation expense of $7.0 8.1 million and $1.8 7.0 million, respectively, related to the issuance of stock options and warrants. As of December 31, 2022 December 31, 2023, there was $17.5 11.2 million of unrecognized compensation cost related to unvested stock-based compensation arrangements that is expected to be recognized over a weighted average period of 2.8 2.5 years.

The fair values of the options granted were estimated based on the Black-Scholes model, using the following assumptions:

	Year Ended December 31,		Year Ended December 31,	
	2022	2021	2023	2022
Expected volatility	74.0% - 77.3%	72.9% - 82.6%	86.4% - 102.2%	74.0% - 77.3%
Risk-free interest rate	1.62% - 4.2%	0.79% - 1.45%	3.5% - 4.5%	1.62% - 4.2%

Expected term (in years)	5.5 - 6.0	5.5 - 9.0	5.5 - 6.1	5.5 - 6.0
Expected dividend yield	0%	0%	0%	0%

Equity-based compensation expense recorded as research and development and general and administrative expenses is as follows (in thousands):

	December 31,	
	2022	2021
Research and development	$ 2,859	$ 600
General and administrative	4,181	1,191
Total equity-based compensation	$ 7,040	$ 1,791

	December 31,	
	2023	2022
Research and development	$ 4,204	$ 2,859
General and administrative	3,855	4,181
Total equity-based compensation	$ 8,059	$ 7,040

We did not recognize any tax benefits for stock-based compensation during the years ended December 31, 2023 and 2022.

13. 12. Income Taxes

We are subject to U.S. federal, state and foreign corporate income taxes. Our loss before provision (benefit) for income taxes for the years ended December 31, 2022 December 31, 2023 and 2021 2022 consisted of the following (in thousands):

	Year Ended December 31,		Year Ended December 31,	
	2022	2021	2023	2022
Domestic	$ (1,885)	$ 206	$ 2,365	$ (1,885)
Foreign	(68,300)	(68,017)	(87,596)	(68,300)
Total	$ (70,185)	$ (67,811)	$ (85,231)	$ (70,185)

Our provision for income taxes consists of the following (in thousands):

	Year Ended December 31,	
	2022	2021
Current:		
Federal	$ 1,059	$ 114
State	86	23
Foreign	52	18
	1,197	155
Deferred:		
Federal	76	(72)
State	—	(15)
Foreign	—	—
	76	(87)
Total provision for income taxes	$ 1,273	$ 68

	Year Ended December 31,

	2023	2022
Current:		
Federal	$ 439	$ 1,059
State	374	86
Foreign	39	52
	852	1,197
Deferred:		
Federal	—	76
State	—	—
Foreign	—	—
	—	76
Total provision for income taxes	$ 852	$ 1,273

Reconciliation of Effective Tax Rate

Our effective tax rate for the years ended December 31, 2022 December 31, 2023 and 2021 2022 is different from the statutory rate in the U.S. primarily due to the valuation allowance against deferred tax assets as a result of insufficient sources of income. The reconciliation of the statutory income tax rate to our effective income tax rate is as follows:

	Year Ended December 31,		Year Ended December 31,	
	2022	2021	2023	2022
Income tax benefit at the statutory rate	21.0%	21.0%	21.0%	21.0%
Permanent differences	0.7	(6.5)	1.0	0.7
Difference in tax rate	1.0	1.0	1.0	1.0
R&D Deduction	4.0	—	1.1	4.0
Change in valuation allowance	(27.4)	(15.6)	(24.7)	(27.4)
Prior period adjustments			(0.2)	(1.0)
Other	(1.1)	—	(0.2)	(0.1)
Total	(1.8)%	(0.1)%	(1.0)%	(1.8)%

Deferred Taxes

Deferred tax assets and liabilities represent future tax consequences of temporary differences between the financial statement carrying amounts and the tax basis of assets and liabilities and for loss carryforwards using enacted tax rates expected to be in effect in the years in which the differences reverse. A valuation allowance is recorded when it is more likely than not

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that some or all of the deferred tax assets will not be realized. The principal components of the Company's deferred tax assets consisted of the following (in thousands):

	December 31,		December 31,	
	2022	2021	2023	2022
Deferred tax assets:				
Net operating loss carryforwards	$ 31,338	$ 14,693	$ 50,343	$ 31,338
Equity-based compensation expense	1,828	345	3,602	1,828
Accrued compensation	21	88	33	21
ROU Lease Liability	618	—	526	618
Capitalized R&D	1,231	—	3,348	1,231
Other	529	73	529	529
Total deferred tax assets	$ 35,565	$ 15,199	$ 58,381	$ 35,565
Valuation allowance	(34,984)	(15,112)	(57,902)	(34,984)
Net deferred tax assets	$ 581	$ 87	$ 479	$ 581

ROU Lease Asset	567	—	441	567
Fixed Assets			26	13
Other Liabilities	14	—	12	1
Total deferred tax liabilities	581	—	479	581
Net deferred tax asset (liability)	$ —	$ 87	$ —	$ —

In 2017, the U.S. enacted the Tax Cuts and Jobs Act (the 2017 Tax Act), which contained a provision that requires capitalization and amortization of research and development expenses for tax purposes starting in 2022. Previously, these expenses could be deducted in the year incurred. The implementation of this provision increased our deferred tax asset and valuation allowance by approximately $2.1 million and $1.2 million in for the years ended December 31, 2023 and 2022.

We determine whether it is more likely than not that a tax position will be sustained upon examination. If it is not more likely than not that a position will be sustained, none of the benefit attributable to the position is recognized. The tax benefit to be recognized for any tax position that meets the more likely than not recognition threshold is calculated as the largest amount that is more than 50%.

When realization of a deferred tax asset is more likely than not to occur, the benefit related to the deductible temporary differences attributable to operations is recognized as a reduction of income tax expense. Valuation allowances are provided against deferred tax assets when, based on all available evidence, it is considered more likely than not that some portion or all of the recorded deferred tax assets will not be realized in future periods. We cannot be certain that future income in Denmark will be sufficient to realize the Company's deferred tax assets. Accordingly, a full valuation allowance has been provided against our net deferred tax assets in Denmark. We have also provided a full valuation allowance against our net deferred tax assets in the U.S. for IO Bio US, Inc. The Company's valuation allowance increased by $22.9 million and $19.9 million in 2022. for the years ended December 31, 2023 and 2022, respectively. The increase in for the years ended December 31, 2023 and 2022 is primarily the result of an increase in net operating loss carryforwards (NOL carryforwards) in Denmark.

Available Carryforward Tax Losses

As of December 31, 2022 December 31, 2023, we had NOL carryforwards of approximately $140.5 228.5 million that can be carried forward indefinitely according to Danish Tax Authority regulations.

Uncertain Tax Positions

We determine our uncertain tax positions based on whether and how much of a tax benefit taken by us in our tax filings is more likely than not to be sustained upon examination by the relevant income tax authorities. We determine whether it is more likely than not that a tax position will be sustained upon examination. If it is not more likely than not that a position will be sustained, none of the benefit attributable to the position is recognized. The tax benefit to be recognized for any tax position that meets the more likely than not recognition threshold is calculated as the largest amount that is more than 50%.

We have reviewed the tax positions taken, or to be taken, in our tax returns for all tax years currently open to examination by the Danish Tax Authority. As of December 31, 2022 December 31, 2023 and 2021, 2022, we have not recorded an uncertain tax position liability.

Tax filings in Denmark remain subject to examination by the Danish Tax Authority. As of December 31, 2022 December 31, 2023, tax years 2019 2020 and forward were generally open to examination by the Danish Tax Authority.

Tax Credits

As of September 30, 2023, we have elected to claim a research and development tax credit on the federal income tax return filed for the year ended December 31, 2022. We plan to continue to make this election on the federal income tax return filed for the year ended December 31, 2023 based on law currently enacted, and will continue to monitor impacts of proposed or enacted law changes on the cost to benefit of making this election. The Company included $1.0 million in research and development tax credits in the U.S. provision for income taxes for the year ended December 31, 2023.

Other Tax Matters

The Company recognizes accrued interest related to unrecognized tax benefits and penalties as income tax expense. expense in the statements of operations. The Company does not have any material unrecognized tax benefits which would affect the effective tax rate, if recognized. The Company does not have any unrecognized tax benefits which would reverse within the next twelve months.

The Company is eligible for the Danish enhanced research and development tax allowance, providing for an increase in the deductible value of the amount of certain R&D expenditures. For 2019, the deduction is set at 101.5%. Furthermore, the deduction for R&D expenditures is set at 130% for 2020 through 2022, 108% for 2023 through 2025, and 110% for 2026.

The tax allowance is reported as a reduction to research and development expense in the statements of operations. For the years ended December 31, 2022 December 31, 2023 and 2021, 2022, we applied for refundable tax credit of 25 25.0 million DKK for each year the years ended December 31, 2023 and 2022 and a receivable was recorded for $0.8 million in each year, respectively.

14. 13. Net Loss Per Share

Basic and diluted net loss per ordinary common share is calculated as follows (in thousands except share and per share amounts):

	Year Ended December 31,		Year Ended December 31,	
	2022	2021	2023	2022
Net loss	$ (71,458)	$ (67,879)	$ (86,083)	$ (71,458)
Cumulative dividends on Class B and C preference shares	—	(7,108)		
Net loss attributable to common shareholders	$ (71,458)	$ (74,987)	$ (86,083)	$ (71,458)
Net loss per common share, basic and diluted	$ (2.48)	$ (17.30)	$ (1.98)	$ (2.48)
Weighted-average number of shares used in computing net loss per common share, basic and diluted	28,815,267	4,335,629	43,539,976	28,815,267

The following outstanding potentially dilutive securities have been excluded from the calculation of diluted net loss per Class A ordinary common share, as their effect is anti-dilutive:

	December 31,	
	2022	2021
Convertible preference shares	—	—
Stock options to purchase common stock	3,920,172	3,071,613
Stock warrants to purchase Class A ordinary shares	—	—

	December 31,	
	2023	2022
Stock options to purchase common stock	5,851,923	3,920,172
Warrants issued in Private Placement	37,065,647	—

15. 14. Subsequent Events

We have evaluated subsequent events through the date on which the consolidated financial statements were issued. The Company has concluded that no subsequent events have occurred that require disclosure to the consolidated financial statements.

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

None.

Item 9A. Controls and Procedures.

Management's Evaluation of our Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer Chief Financial Officer and Chief Accounting Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2022 December 31, 2023. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, mean controls and other procedures of a company that are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company on the reports that it files or submits under the Exchange Act is accumulated and communicated to management, including, our principal executive and principal financial officers, 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 objectives and management necessarily applies its judgement 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, 2022 December 31, 2023 our Chief Executive Officer Chief Financial Officers and Chief Accounting Financial Officer concluded that our disclosure controls and procedures were effective as of December 31, 2022 December 31, 2023.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting as defined under the Exchange Act and by the Public Company Accounting Oversight Board (United States), such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis.

The Company previously disclosed a material weakness in internal control over financial reporting as of December 31, 2021 in Item 9A. of our Annual Report in Form 10-K for the year ended December 31, 2021 related to our financial statement close process, primarily related to the lack of required finance capacity, knowledge or expertise to perform the financial statement close in a timely and accurate manner or to account for certain complex areas of U.S. GAAP.

Remediated Material Weakness

Remediation of the previously identified material weakness and the strengthening of our internal control over financial reporting environment was a priority of the Company during 2022. These efforts included the hiring of a Chief Financial Officer in the fourth quarter of 2022, promotion of our VP of Finance to Chief Accounting Officer in the second quarter of 2022 and the hiring of four other qualified accounting and financial reporting personnel during the 2022 period. In addition, the Company implemented and tested the design and operating effectiveness of new and existing controls related to the previously identified material weakness, as follows:

- The Company enhanced its financial close process by introducing additional layers of independent reviews by appropriately qualified individuals and improving the precision and timeliness of reviews applied to financial statement account balances, journal entries, and expense accruals, including tasks relevant to financial reporting that are initiated or executed by third-party service providers. Additionally, the Company enhanced the level of evidence of review required to be maintained to evidence the operation of controls.
- In order to enhance the confirmation of the completeness and accuracy of the Company's quarterly and annual SEC filings, including the Company's quarterly and financial statements and corresponding disclosures, a process was instituted during 2022 whereby drafts of quarterly and annual financial statements and disclosures

were distributed to both external SEC counsel and the executive management team for review of completeness and accuracy.

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rule 13a-15(f) and 15d-15(f) of the Securities Exchange Act of 1934, as amended. Our internal control over financial reporting is a process designed to provide reasonable assurance to our management and board of directors regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes policies and procedures that: (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of our assets; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with U.S. GAAP, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our 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, errors or fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected. Also, projections of any evaluations 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.

Management assessed the effectiveness of our internal control over financial reporting as of December 31, 2022 December 31, 2023 based on the framework set forth by the Committee of Sponsoring Organizations of the Treadway Commissions in Internal Control-Integrated Framework. Based on that assessment, management has concluded that our internal control over financial reporting was effective as of December 31, 2022 December 31, 2023.

Attestation Report of the Registered Public Accounting Firm

This Annual Report on Form 10-K does not include an attestation report of our independent registered public accounting firm due to an exemption established by the JOBS Act for “emerging growth companies.”

Changes in Internal Control over Financial Reporting

Other than the changes described above in "Remediated Material Weakness", there There has been no change in our internal control over financial reporting as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act during the year ended December 31, 2022 December 31, 2023 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

None.

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

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required under this item is incorporated herein by reference to the Company’s definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the Securities and Exchange Commission not later than 120 days after the close of the Company’s fiscal year ended December 31, 2022 December 31, 2023.

Item 11. Executive Compensation.

The information required under this item is incorporated herein by reference to the Company’s definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the Securities and Exchange Commission not later than 120 days after the close of the Company’s fiscal year ended December 31, 2022 December 31, 2023.

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

The information required under this item is incorporated herein by reference to the Company’s definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the Securities and Exchange Commission not later than 120 days after the close of the Company’s fiscal year ended December 31, 2022 December 31, 2023.

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

The information required under this item is incorporated herein by reference to the Company’s definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the Securities and Exchange Commission not later than 120 days after the close of the Company’s fiscal year ended December 31, 2022 December 31, 2023.

Item 14. Principal Accounting Fees and Services.

The information required under this item is incorporated herein by reference to the Company's definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the Securities and Exchange Commission not later than 120 days after the close of the Company's fiscal year ended December 31, 2022 December 31, 2023.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(1) For a list of the financial statements included herein, see Index to the Consolidated Financial Statements on page 139 of this Annual Report on Form 10-K, incorporat this Item by reference.

(2) Financial statement schedules have been omitted because they are either not required or not applicable or the information is included in the consolidated fi statements or the notes thereto.

(3) Exhibits:

Exhibit Number	Description
3.1	Amended and Restated Certificate of Incorporation of IO Biotech, Inc. (filed as an exhibit to our Amendment No. 2 to Registration Statement Quarterly Report on Form S-1/A 10-Q dated November 1, 2021 August 11, 2023 and incorporated herein by reference)
3.2	Form of Amended and Restated Bylaws of IO Biotech, Inc. (filed as an exhibit to our Amendment No. 2 to Registration Statement on Form S-1/A dated November 1, 2021 and incorporated herein by reference)
4.1	Form of Common Stock Certificate (filed as an exhibit to our Amendment No. 2 to Registration Statement on Form S-1/A dated November 1, 2021 and incorporated herein by reference)
4.2*	Description of Capital Stock
4.3	Indenture (filed as an exhibit to our Registration Statement on Form S-3 dated February 3, 2023 and incorporated herein by reference)
4.4	Form of Warrant (filed as an exhibit to our Form 8-K dated August 7, 2023 and incorporated herein by reference)
10.1†	Form of Indemnification Agreement (filed as an exhibit to our Amendment No. 2 to Registration Statement on Form S-1/A dated November 1, 2021 and incorporated herein by reference)
10.2†	Form of IO Biotech, Inc. 2021 Equity and Incentive Plan and related form agreements (filed as an exhibit to our Amendment No. 2 to Registration Statement on Form S-1/A dated November 1, 2021 and incorporated herein by reference)
10.3†	Form of IO Biotech, Inc. 2021 Employee Stock purchase Plan and related form agreements (filed as an exhibit to our Amendment No. 2 to Registration Statement on Form S-1/A dated November 1, 2021 and incorporated herein by reference)
10.4#	Option Assignment Agreement, dated as of January 2, 2015, by and between IO Biotech ApS and Herlev Hospital (filed as an exhibit to our Amendment No. 1 to Registration Statement on Form S-1/A dated October 26, 2021 and incorporated herein by reference)
10.5	Addendum I to Option Assignment Agreement, dated as of May 2, 2016, by and between IO Biotech ApS and Herlev Hospital (filed as an exhibit to our Amendment No. 1 to Registration Statement on Form S-1/A dated October 26, 2021 and incorporated herein by reference)
10.6#	Framework Assignment Agreement, dated as of May 2, 2016, by and between IO Biotech ApS and Herlev Hospital (filed as an exhibit to our Amendment No. 1 to Registration Statement on Form S-1/A dated October 26, 2021 and incorporated herein by reference)
10.7#	Assignment Agreement, dated as of January 2, 2017, by and between IO Biotech ApS and Herlev and Gentofte Hospital (field as an exhibit to our Amendment No. 1 to Registration Statement on Form S-1/A dated October 26, 2021 and incorporated herein by reference)
10.8#	Option Assignment Agreement, dated as of March 27, 2017, by and between IO Biotech ApS and Herlev and Gentofte Hospital (filed as an exhibit to our Amendment No. 1 to Registration Statement on Form S-1/A dated October 26, 2021 and incorporated herein by reference)
10.9#	1st Amendment to Option Assignment Agreement, dated as of December 7, 2018, by and between IO Biotech ApS and Herlev and Gentofte Hospital (filed as an exhibit to our Amendment No. 1 to Registration Statement on Form S-1/A dated October 26, 2021 and incorporated herein by reference)
10.10	2nd Amendment to Option Assignment Agreement, dated as of December 7, 2018, by and between IO Biotech ApS and Herlev and Gentofte Hospital (filed as an exhibit to our Amendment No. 1 to Registration Statement on Form S-1/A dated October 26, 2021 and incorporated herein by reference)
10.11	Agreement on Payment for Specific Services, dated as of January 27, 2021, by and between IO Biotech ApS and Herlev and Gentofte Hospital (filed as an exhibit to our Amendment No. 1 to Registration Statement on Form S-1/A dated October 26, 2021 and incorporated herein by reference)

10.12#	Clinical Trial Collaboration and Supply Agreement, dated September 7, 2021, by and among IO Biotech ApS, MSD International GmbH and MSD International Business GmbH (filed as an exhibit to our Amendment No. 1 to Registration Statement on Form S-1/A dated October 26, 2021 and incorporated herein by reference)
10.13	Investors' Rights Agreement, dated October 29, 2021, by and among IO Biotech, Inc. and the Investors and Key Holders party thereto (filed as an exhibit to our Amendment No. 2 to Registration Statement on Form S-1/A dated November 1, 2021 and incorporated herein by reference)

10.14†	Service Agreement, dated August 21, 2017, by and between IO Biotech ApS and Mai-Britt Zocca (filed as an exhibit to our Amendment No. 1 to Registration Statement on Form S-1/A dated October 26, 2021 and incorporated herein by reference)
10.15†	Addendum to Service Agreement, dated April 1, 2021, by and between IO Biotech ApS and Mai-Britt Zocca (filed as an exhibit to our Amendment No. 1 to Registration Statement on Form S-1/A dated October 26, 2021 and incorporated herein by reference)
10.16†	Service Agreement, dated August 21, 2017, by and between IO Biotech ApS and Eva Ehrnrooth (filed as an exhibit to our Amendment No. 1 to Registration Statement on Form S-1/A dated October 26, 2021 and incorporated herein by reference)
10.17†	Addendum to Service Agreement, dated April 1, 2021, by and between IO Biotech ApS and Eva Ehrnrooth (filed as an exhibit to our Amendment No. 1 to Registration Statement on Form S-1/A dated October 26, 2021 and incorporated herein by reference)
10.18#	Clinical Trial Collaboration and Supply Agreement by and among IO Biotech ApS, MSD International GmbH, and MSD International Business GmbH, dated as of November 30, 2021 (filed as an exhibit to our Current Report on Form 8-K dated November 30, 2021 and incorporated herein by reference)
10.19*†	Letter Agreement, dated as of October 15, 2022, by and between IO Bio US, Inc. and Amy Sullivan.
10.20	Common Stock Sales Agreement, dated as of February 15, 2023, by and between IO Biotech, Inc. and Cowen and Company LLC (filed as an exhibit to our Form 8-K dated February 15, 2023 and incorporated herein by reference).
10.21	Securities Purchase Agreement, dated as of August 7, 2023, by and among IO Biotech, Inc. and the Purchasers thereto (filed as an exhibit to our Form 8-K dated August 7, 2023 and incorporated herein by reference)
10.22	Registration Rights Agreement, dated as of August 7, 2023, by and among IO Biotech, Inc. and the Purchasers thereto (filed as an exhibit to our Form 8-K dated August 7, 2023 and incorporated herein by reference)
21.1	List of subsidiaries (filed as an exhibit to our Amendment No. 1 to Registration Statement on Form S-1/A dated October 26, 2021 and incorporated herein by reference)
23.1*	Consent of EY Godkendt Revisionspartnerselskab, independent registered public accounting firm
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.3*	Certification of Principal Accounting Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
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.
32.3* 97.1*	Certification Policy on Recoupment of Principal Accounting Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 Incentive Compensation, dated September 20, 2023, of the Sarbanes-Oxley Act of 2002. IO Biotech Inc.
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.
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 (embedded within the Inline XBRL document)

* Filed herewith.

† Indicates a management contract or compensatory plan or arrangement.

Portions of the exhibit have been or will be excluded because it is both not material and is the type of information that the registrant treats as private or confidential.

Item 16. Form 10-K Summary

None.

SIGNATURES

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

IO Biotech, Inc.

Date: March 14, 2023 March 5, 2024

By: /s/ Mai-Britt Zocca

Mai-Britt Zocca, Ph.D.
Chief Executive Officer and Director
(Principal Executive Officer)

Each person whose signature appears below constitutes and appoints Mai-Britt Zocca and Amy Sullivan, and each of them, his or her true and lawful agent, proxy and attorney-in-fact, 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 file with the Securities and Exchange Commission this Form 10-K and any and all amendments and exhibits thereto, and all documents in connection therewith, granting unto each such attorney-in-fact and agent full power and authority to do and perform each and every act and thing necessary or appropriate to be done, as fully for all intents and purposes as he or she might or could do in person, hereby approving, ratifying and confirming all that such agent, proxy and attorney-in-fact or any of his or her substitutes may lawfully do or cause to be done by virtue hereof.

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

Name	Title	Date
/s/ Mai-Britt Zocca, Ph.D. **Mai-Britt Zocca, Ph.D.**	Chief Executive Officer and Director (Principal Executive Officer)	March 14, 2023 March 5, 2024
/s/ Amy Sullivan, M.B.A. **Amy Sullivan, M.B.A.**	Chief Financial Officer (Principal Financial Officer)	March 14, 2023 March 5, 2024
/s/ Brian Burkavage **Brian Burkavage**	Chief Accounting Officer (Principal Accounting Officer)	March 14, 2023
/s/ Peter Hirth, Ph.D. **Peter Hirth, Ph.D.**	Chairman of the Board	March 14, 2023 March 5, 2024
/s/ Kathleen Sereda Glaub, M.B.A. **Kathleen Sereda Glaub, M.B.A.**	Director	March 14, 2023 March 5, 2024
/s/ Christian Elling, Ph.D. **Christian Elling, Ph.D.**	Director	March 14, 2023 March 5, 2024
/s/ Helen Collins, MD **Helen Collins, MD**	Director	March 5, 2024
/s/ Priyanka Belawat, Ph.D. **Priyanka Belawat, Ph.D.**	Director	March 14, 2023
/s/ Jack B. Nielsen	Director	March 14, 2023 March 5, 2024

Jack B. Nielsen		
/s/ Vanessa Malier Heidi Hunter **Vanessa Malier Heidi Hunter**	Director	March 14, 2023 March 5, 2024
/s/ David V. Smith, M.B.A. **David Smith, M.B.A.**	Director	March 14, 2023 March 5, 2024

Exhibit 4.2

DESCRIPTION OF CAPITAL STOCK

*The following summary describes the capital stock of IO Biotech, Inc. (the "Company," "we," "us," and "our") and the material provisions of our amended and restated certificate of incorporation and our amended and restated bylaws, the investors' rights agreement to which we and certain stockholders are parties (the "**IRA**") and of the General Corporation Law of the State of Delaware. Because the following is only a summary, it does not contain all of the information that may be important to you. For a complete description, you should refer to our amended and restated certificate of incorporation, amended and restated bylaws, and the IRA, copies of which are incorporated by reference as exhibits to our Annual Report on Form 10-K.*

As of December 31, 2022 December 31, 2023, IO Biotech, Inc. ("IO Biotech") had common stock, $0.001 par value per share, registered under Section 12 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and listed on The Nasdaq Global Select Market under the trading symbol "IOBT."

General

Our amended and restated certificate of incorporation authorizes 300,000,000 shares of common stock, $0.001 par value per share, and 5,000,000 shares of undesignated preferred stock, $0.001 par value per share, the rights, preferences and privileges of which may be designated from time to time by our board of directors.

As of December 31, 2022 December 31, 2023, we had outstanding 28,815,267 65,880,914 shares of common stock.

Common Stock

Dividend Rights

Subject to preferences that may apply to shares of preferred stock outstanding at the time, the holders of outstanding shares of our common stock are entitled to receive dividends out of funds legally available if our board of directors, in its discretion, determines to issue dividends and only then at the times and in the amounts that our board of directors may determine.

Voting Rights

The holders of our common stock are entitled to one vote per share. Stockholders do not have the ability to cumulate votes for the election of directors. Our amended and restated certificate of incorporation and bylaws provide for a classified board of directors consisting of three classes of approximately equal size, each serving staggered three-year terms. Only one class of directors will be elected at each annual meeting of our stockholders, with the other classes continuing for the remainder of their respective three-year terms.

No Preemptive or Similar Rights

Our common stock is not entitled to preemptive rights and is not subject to redemption or sinking fund provisions.

Right to Receive Liquidation Distributions

Upon our liquidation, dissolution or winding-up, the assets legally available for distribution to our stockholders would be distributable ratably among the holders of our common stock and any participating preferred stock outstanding at that time, subject to prior satisfaction of all outstanding debt and liabilities and the preferential rights of and the payment of liquidation preferences, if any, on any outstanding shares of preferred stock.

Preferred Stock

Pursuant to our amended and restated certificate of incorporation, our board of directors is authorized, subject to limitations prescribed by Delaware law, to issue preferred stock in one or more series, to establish from time to time the number of shares to be included in each series and to fix the designation, powers, preferences and rights of the shares of each series and any of its qualifications, limitations or restrictions, in each case without further vote or action by our stockholders. Our board of directors can also increase or decrease the number of shares of any series of preferred stock, but not below the number of shares of that series then outstanding, without any further vote or action by our stockholders. Our board of directors may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of our common stock. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deferring or preventing a change in our control and might adversely affect the market price of our common stock and the voting and other rights of the holders of our common stock. We have no current plan to issue any shares of preferred stock.

Warrants and Options

As of December 31, 2022 December 31, 2023, we had outstanding options and warrants to purchase an aggregate of 2,137,286 42,917,570 shares of common stock, with a weighted-average exercise price of $12.90 per share and outstanding options to purchase an aggregate of 1,782,886 shares of common stock, with a weighted-average exercise price of $8.22 $3.11 per share.

Registration Rights

Certain holders of shares of our common stock, or their permitted transferees, are entitled to rights with respect to the registration of these shares under the Securities Act of 1933, as amended (the "Securities Act"). These shares are referred to as registrable securities. These rights are provided under the terms of our IRA, and are described in additional detail below.

Demand Registration Rights

The holders of registrable securities are entitled to certain demand registration rights. Upon the written request of the holders of a majority of our registrable securities then outstanding that we file a registration statement under the Securities Act covering at least 40% of our registrable securities then outstanding, we are obligated to register the sale of all registrable securities that the holders may request in writing to be registered. We are required to effect no more than one registration statement that is declared or ordered effective. We may postpone the filing of a registration statement for up to 120 days once in a 12-month period if in the good faith judgment of our Board of Directors such registration would be seriously detrimental to us.

Piggyback Registration Rights

The holders of registrable securities are entitled to certain piggyback registration rights.

If we register any of our securities for public sale, either for our own account or for the account of other security holders, we will also have to register all registrable securities that the holders of such securities request in writing be registered. This piggyback registration right does not apply to a registration relating to any of our stock plans, stock purchase or similar plan, a transaction under Rule 145 of the Securities Act or a registration related to stock issued upon conversion of debt securities. We, based on consultation with the underwriters of any underwritten offering will have the right to limit the number of shares registered by these holders if the underwriters determine that including all registrable securities will jeopardize the success of the offering.

Form S-3 Registration Rights

The holders of at least 30% of the registrable securities then outstanding are entitled to certain registration rights on Form S-3. The holders of these shares can request that we register all or a portion of their shares on Form S-3 if we are eligible to file a registration statement on Form S-3 and the aggregate price to the public of the shares offered is in excess of $10.0 million. We are required to effect no more than two Form S-3 registration statements that are declared or ordered effective in any 12-month period. We may postpone the filing of a registration statement for up

to 120 days not more than once in a 12-month period if in the good faith judgment of our Board of Directors such registration would be seriously detrimental to us.

Anti-Takeover Provisions

The provisions of the DGCL, our amended and restated certificate of incorporation and our bylaws could have the effect of delaying, deferring or discouraging another person from acquiring control of our company. These provisions, which are summarized below, are expected to discourage certain types of coercive takeover practices and inadequate takeover bids and encourage persons seeking to acquire control of our company to first negotiate with our board of directors. We believe that the benefits of increased protection of our potential ability to negotiate with an unfriendly or unsolicited acquirer outweigh the disadvantages of discouraging a proposal to acquire us because negotiation of these proposals could result in an improvement of their terms.

Section 203 of the DGCL

We are subject to the provisions of Section 203 of the DGCL regulating corporate takeovers. In general, Section 203 prohibits a publicly held Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a three-year period following the date that this stockholder becomes an interested stockholder, unless the business combination is approved in a prescribed manner. Under Section 203, a business combination between a corporation and an interested stockholder is prohibited unless it satisfies one of the following conditions:

- before the stockholder became interested, our board of directors approved either the business combination or the transaction, which resulted in the stockholder becoming an interested stockholder;
- upon consummation of the transaction, which resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding, shares owned by persons who are directors and also officers, and employee stock plans in some instances, but not the outstanding voting stock owned by the interested stockholder; or
- at or after the time the stockholder became interested, the business combination was approved by our board and authorized at an annual or special meeting of the stockholders by the affirmative vote of at least two-thirds of the outstanding voting stock, which is not owned by the interested stockholder.

Section 203 defines a business combination to include:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, lease, pledge or other disposition involving the interested stockholder of 10% or more of the assets of the corporation;
- subject to exceptions, any transaction that results in the issuance of transfer by the corporation of any stock of the corporation to the interested stockholder;
- subject to exceptions, any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder; and
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 defines an interested stockholder as any entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with or controlling or controlled by the entity or person.

Amended and Restated Certificate of Incorporation and Bylaw Provisions

Our amended and restated certificate of incorporation and our bylaws include a number of provisions that may have the effect of deterring hostile takeovers, or delaying or preventing changes in control of our management team or changes in our board of directors or our governance or policy, including the following:

Board Vacancies

Our amended and restated certificate of incorporation and bylaws authorize generally only our board of directors to fill vacant directorships resulting from any cause or created by the expansion of our board of directors. In addition, the number of directors constituting our board of directors may be set only by resolution adopted by a majority vote of our entire board of directors. These provisions prevent a stockholder from increasing the size of our board of directors and gaining control of our board of directors by filling the resulting vacancies with its own nominees.

Classified Board

Our amended and restated certificate of incorporation and bylaws provide that our board of directors is classified into three classes of directors. The existence of a classified board of directors could delay a successful tender offeror from obtaining majority control of our board of directors, and the prospect of that delay might deter a potential offeror.

Directors Removed Only for Cause

Our amended and restated certificate of incorporation provides that stockholders may remove directors only for cause.

Supermajority Requirements for Amendments of Our Amended and Restated Certificate of Incorporation and Bylaws

Our amended and restated certificate of incorporation further provides that the affirmative vote of holders of at least two-thirds of the voting power of our outstanding common stock are required to amend certain provisions of our amended and restated certificate of incorporation, including provisions relating to the classified board, the size of the board of directors, removal of directors, special meetings, actions by written consent and designation of our preferred stock. The affirmative vote of holders of at least two-thirds of the voting power of our outstanding common stock are required to amend or repeal our bylaws, although our bylaws may be amended by a simple majority vote of our board of directors.

Stockholder Action; Special Meeting of Stockholders

Our amended and restated certificate of incorporation provides that our stockholders may not take action by written consent, but may only take action at annual or special meetings of our stockholders. As a result, holders of our capital stock would not be able to amend our bylaws or remove directors without holding a meeting of our stockholders called in accordance with our bylaws. Our amended and restated certificate of incorporation and our bylaws provide that special meetings of our stockholders may be called only by a majority of our board of directors, the chairperson of our board of directors, or our chief executive officer, thus prohibiting a stockholder from calling a special meeting. These provisions might delay the ability of our stockholders to force consideration of a proposal or for stockholders to take any action, including the removal of directors.

Advance Notice Requirements for Stockholder Proposals and Director Nominations

Our bylaws provide advance notice procedures for stockholders seeking to bring business before our annual meeting of stockholders or to nominate candidates for election as directors at our annual meeting of stockholders. To be timely, a stockholder's notice generally must be delivered to us not later than the close of business on the 90th day nor earlier than the close of business on the 120th day prior to the first anniversary of the preceding year's annual meeting of stockholders. Our bylaws also specify certain requirements regarding the form and content of a stockholder's notice. With respect to nominations of persons for election to our board of directors, the notice shall provide information about the nominee, including, among other things, name, age, address, principal occupation,

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ownership of our capital stock and whether they meet applicable independence requirements. With respect to the proposal of other business to be considered by our stockholders at an annual meeting, the notice shall provide a brief description of the business desired to be brought before the meeting, the text of the proposal or business, the reasons for conducting such business at the meeting and any material interest in such business by such stockholder and any beneficial owners and associated persons on whose behalf the notice is made, or the proposing persons. In addition, a stockholder's notice must set forth certain information related to the proposing persons, including, among other things:

- the name and address of the proposing persons;
- information as to the ownership by the proposing persons of our capital stock and any derivative interest or short interest in any of our securities held by the proposing persons;
- information as to any material relationships and interest between the proposing persons and us, any of our affiliates and any of our principal competitors;
- a representation that the stockholder is a holder of record of our stock entitled to vote at that meeting and that the stockholder intends to appear in person or by proxy at the meeting to propose such nomination or business; and
- a representation whether the proposing persons intend or are part of a group which intends to deliver a proxy statement or form of proxy to holders of at least the percentage of our outstanding capital stock required to elect the nominee or carry the proposal.

These provisions may preclude our stockholders from bringing matters before our annual meeting of stockholders or from making nominations for directors at our annual meeting of stockholders. We expect that these provisions might also discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of our company.

No Cumulative Voting

The DGCL provides that stockholders are not entitled to the right to cumulate votes in the election of directors unless a corporation's certificate of incorporation provides otherwise. Our amended and restated certificate of incorporation and bylaws do not provide for cumulative voting.

Issuance of Undesignated Preferred Stock

Our board has the authority, without further action by the stockholders, to issue up to 5,000,000 shares of undesignated preferred stock with rights and preferences, including voting rights, designated from time to time by our board of directors. The existence of authorized but unissued shares of preferred stock enables our board of directors to render more difficult or to discourage an attempt to obtain control of us by means of a merger, tender offer, proxy contest or otherwise.

Exclusive Forum

Our amended and restated certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, to the fullest extent permitted by law, the sole and exclusive forum for (1) any derivative action or proceeding brought on our behalf under Delaware law, (2) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders, (3) any action asserting a claim against us or any of our directors, officers or other employees arising pursuant to any provision of the Delaware General Corporation Law or our amended and restated certificate of incorporation or bylaws, (4) any other action against us or any of our directors, officers or other employees asserting a claim that is governed by the internal affairs doctrine shall be the Court of Chancery of the State of Delaware (or, if the Court of Chancery does not have jurisdiction, the federal district court for the District of Delaware) or (5) any other action asserting an "internal corporate claim," as defined in Section 115 of the Delaware General Corporation Law, in all cases subject to the court having jurisdiction over indispensable parties named as defendants. These exclusive-forum provisions do not apply to claims under the Securities Act or the Exchange Act. Any person or entity purchasing or otherwise

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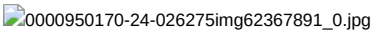
acquiring any interest in our securities shall be deemed to have notice of and consented to this provision. Although we believe these provisions benefit us by providing increased consistency in the application of Delaware law for the specified types of actions and proceedings, the provisions may have the effect of discouraging lawsuits against us or our directors and officers.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Computershare Trust Company, N.A. The transfer agent's address is 150 Royall Street, Canton, Massachusetts 02021, and its telephone number is (800) 962-4284.

Exhibit 10.19



3 October 2022

Ms. Amy Sullivan
[***]
[***]

Re: Offer of Employment

Dear Amy:

I am pleased to offer you full-time employment with IO Bio US, Inc. (the "***Company***"), a subsidiary IO Biotech ApS ("***IO Biotech***"), beginning on October 15, 2022 (the "***Commencement Date***"). As of the Commencement Date you will be employed in the position of Chief Financial Officer, and report to the Chief Executive Officer of IO Biotech. You will perform your duties primarily from your home in Massachusetts, but be subject to necessary travel as may be required from time to time, including regular travel to the New York office as appropriate.

You will receive a base salary at an annual rate of U.S. $425,000, less applicable withholdings, which will be paid in accordance with the Company's normal payroll procedures.

You will be eligible to earn an annual bonus with a target payout equal to 45% of your annual base salary (prorated for 2022). The final bonus amount will be determined based on your performance and the performance of IO Biotech and its subsidiaries, if any, during the calendar year, as determined by the Company. The Company will pay this bonus, to the extent earned, by March 15th of the following calendar year. The bonus is not earned until paid and, except as expressly set forth below, no pro-rated amount will be paid if your employment terminates for any reason prior to the payment date.

IO Biotech shall grant to you, upon and subject to Board of Directors approval as soon as administratively practicable after the Commencement Date, a number of options allowing you to subscribe for such number of shares of IO Biotech that represents 1% of the issued and outstanding shares of IO Biotech as of the Commencement Date, at an exercise price equal to the closing price of IO Biotech shares on the date of grant, and such other terms and conditions as determined by the Board of Directors of IO Biotech. Twenty-five percent of such options will vest on the first anniversary of the Commencement Date, and the remainder will vest on a monthly basis after that over the subsequent 36 months, subject to your continued employment through the applicable vesting date (except as provided below).

During your employment, you will be eligible to participate in the Company's standard benefit plans maintained by the Company and offered to similarly situated U.S. employees from time to time, subject to the terms of such

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plans and generally applicable Company policies. The Company may modify its compensation and benefit plans from time to time in its discretion.

You will be eligible for vacation to be taken at such times as you may select consistent with the Company's policies. In addition, you shall be entitled to such national holidays as observed in the United States pursuant to Company policy.

As a Company employee, you will be expected to abide by all rules and policies of IO Biotech and its subsidiaries (the "***IO Biotech Group***") in place from time to time. As a condition of employment, you must sign and comply with the attached Employee Confidential Information and Inventions Assignment Agreement ("***CIIA***") which prohibits unauthorized use or disclosure of IO Biotech Group proprietary information, among other obligations.

This employment offer is contingent on and subject to the nonexistence of any legally enforceable agreement between you and any other person or entity which would restrict your ability to be employed by the Company. It is the Company's understanding and your express representation that no noncompetition agreements or other post-employment obligations will prevent you from performing the duties of your position. You acknowledge and agree that, as of the Commencement Date, you were not engaged in any other employment, occupation, consulting, or other business activity directly related to the business in which the IO Biotech Group is involved. Moreover, you agree that during the term of your employment with the Company you will not engage in any other employment, occupation, consulting, or other business activity directly related to the business in which the IO Biotech

Group is now involved or becomes involved during the term of your employment or in any other activities that materially conflict with your obligations to the IO Biotech Group, provided that you may with prior written approval of the Chief Executive Officer of IO Biotech, not to be unreasonably withheld, serve on advisory boards or board of directors (or similar advisory or governing bodies) of other companies and organizations (whether industry, non-profit, for profit or other, in each case other than competitors of the IO Biotech Group) as long as such activities do not conflict with the interests of the IO Biotech Group or otherwise materially interfere, individually or in the aggregate, with the performance of your duties to the IO Biotech Group. Similarly, you agree not to utilize any third-party confidential information in performing your duties for the IO Biotech Group.

Your employment relationship with the Company is at-will. You may terminate your employment with the Company at any time and for any reason whatsoever simply by notifying the Chief Executive Officer of IO Biotech in writing at least 30 days prior to the date of such termination. Likewise, subject to the provisions below related to severance, the Company may terminate your employment at any time by notifying you in writing at least 30 days prior to the date of such termination; provided that the Company may terminate your employment immediately upon written notice if such termination is for Cause, as defined below. Your employment at-will status can only be modified in a written agreement signed by you and by the Chief Executive Officer of IO Biotech.

If the Company terminates your employment without Cause or you resign for Good Reason, as such terms are defined below, you shall be entitled to receive: (i) severance pay in an amount equal to 12 months of your then current base salary, payable in substantially equal installments over the 12-month period following your termination date; (ii) any unpaid bonus for the prior year, as authorized by the Company, payable within 30 days after your termination date; (iii) if you elect to continue your health care benefits under COBRA or any similar state law following your termination date, then during the first 12 months of such coverage your health premiums shall be equal to those paid by similarly situated active employees and (iv) 25% of the number of options that are unvested as of the date of your termination shall become vested and exercisable as of the date of your termination of employment. In addition, if such termination occurs within 24 months after a Change of Control (as such term is defined in IO Biotech's Articles of Association), then all outstanding options that are unvested immediately prior to such termination shall become fully vested and exercisable upon such termination. To be eligible to receive any severance benefits hereunder, you must execute a reasonable and customary separation and general

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release of claims agreement (the "***Release Agreement***") in a form to be provided by the Company (which will include, at a minimum, a release of all releasable claims, reasonable obligations to cooperate, a non-disparagement obligation, and reaffirmation of your continuing non-compete and other continuing obligations to the IO Biotech Group) within 21 days following your termination and not revoke such Release Agreement within seven days after it has been executed.

For purposes of this letter agreement:

"***Cause***" means the occurrence of any of the following events: (i) your willful failure substantially to perform your duties and responsibilities to the IO Biotech Group or your violation of an IO Biotech Group policy; (ii) your commission of any act of fraud, embezzlement, dishonesty or any other willful misconduct that has caused or is reasonably expected to result in injury to the IO Biotech Group; (iii) your unauthorized use or disclosure of any proprietary information or trade secrets of the IO Biotech Group or any other party to whom you owe an obligation of nondisclosure as a result of your relationship with the IO Biotech Group; or (iv) your breach of any of your obligations under any written agreement or covenant with the IO Biotech Group. The determination that a termination of your employment is either for Cause or without Cause will be made by the Chief Executive Officer of IO Biotech, in her sole discretion.

*"**Good Reason**"* means any of the following actions taken by the Company without your consent: (i) the Company's breach of any material obligations to you under this letter agreement or any other material agreement to which you and the Company are parties; (ii) a requirement by the Company that you relocate your principal employment responsibilities to a location that is more than 50 miles from the location at which your principal employment responsibilities are then being performed; (iii) an adverse change in your reporting relationship, authority or areas of responsibility as are commensurate with your position; provided, however, that it shall not be considered "Good Reason" if, following a Change in Control, either (a) the Company continues as a separate legal entity or business unit and you hold the same position in such legal entity or business unit as you held before such Change in Control, or (b) you hold a position with authority, duties, function or responsibilities comparable (though not necessarily identical, in view of the relative sizes of the Company and the entity involved in the Change in Control) to those that you held prior to such Change in Control; or (iv) a material reduction in your base salary, except in the case of across-the-board salary reductions based on the Company's financial performance and similarly affecting all other executives of the Company at your level of employment; provided, however, that no such action taken by the Company shall constitute Good Reason unless (A) you provide written notice to the Chief Executive Officer of the Company stating your objection to such action

not later than 30 days after it initially occurs, (B) the Company shall have failed to remedy such action within 30 days after receipt of such notice and (C) you resign from employment within 60 days after the expiration of such remediation period.

This letter is intended to comply with the requirements of Section 409A of the Internal Revenue Code of 1986, as amended (the "Code"), and shall be interpreted and construed consistently with such intent. The payments to you are also intended to be exempt from Section 409A of the Code to the maximum extent possible, under either the separation pay exemption pursuant to Treasury regulation §1.409A-1(b)(9)(iii) or as short-term deferrals pursuant to Treasury regulation §1.409A-1(b)(4), and for this purpose each payment shall constitute a "separately identified" amount within the meaning of Treasury Regulation §1.409A-2(b)(2). In the event the terms of this letter would subject you to taxes or penalties under Section 409A of the Code ("409A Penalties"), you and the Company shall cooperate diligently to amend the terms of this letter to avoid such 409A Penalties, to the extent possible; provided that in no event shall the Company be responsible for any 409A Penalties that arise in connection with any amounts payable under this letter. To the extent any amounts under this letter are payable by reference to your "termination of employment," such term shall be deemed to refer to your "separation from service," within the meaning of Section 409A of the Code. Notwithstanding any other provision in this letter, if you are a "specified employee," as defined in Section 409A of the Code, as of the date of your separation from service, then to the extent any amount payable to you (i) constitutes the payment of nonqualified deferred compensation, within the meaning of Section 409A of the Code, (ii) is payable upon your separation from service

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and (iii) under the terms of this letter would be payable prior to the six-month anniversary of the your separation from service, such payment shall be delayed until the earlier to occur of (a) the first business day following the six-month anniversary of the separation from service and (b) the date of your death. Any reimbursement or advancement payable to you pursuant to this letter or otherwise shall be conditioned on the submission by you of all expense reports reasonably required by the Company under any applicable expense reimbursement policy, and shall be paid to you within 30 days following receipt of such expense reports, but in no event later than the last day of the calendar year following the calendar year in which you incurred the reimbursable expense. Any amount of expenses eligible for reimbursement, or in-kind benefit provided, during a calendar year shall not affect the amount of expenses eligible for reimbursement, or in-kind benefit to be provided, during any other calendar year. The right to any reimbursement or in-kind benefit pursuant to this letter or otherwise shall not be subject to liquidation or exchange for any other benefit.

For purposes of federal immigration law, you will be required to provide to the Company, or the Company's designee, documentary evidence of your identity and eligibility for employment in the United States. Such documentation must be provided to the Company or its designee within three (3) business days of the Commencement Date, or our employment relationship with you may be terminated and such termination shall be deemed to be for "Cause."

To ensure the timely and economical resolution of disputes that may arise in connection with your employment with the Company, you and the Company agree that any and all disputes, claims, or causes of action arising from or relating to the CIIA enforcement, breach, performance, negotiation, execution, or interpretation of this letter agreement, the CIIA, your employment, or the termination of your employment, including but not limited to all statutory claims, will be resolved pursuant to the Federal Arbitration Act, 9 U.S.C. §1-16, and to the fullest extent permitted by law, by final, binding and confidential arbitration by a single arbitrator conducted in the Washington, D.C. metropolitan area by Judicial Arbitration and Mediation Services Inc. ("***JAMS***") under the then applicable JAMS rules (at the following web address: https://www.jamsadr.com/rules-employment-arbitration/). A hard copy of the rules will be provided to you upon request. **By agreeing to this arbitration procedure, both you and the Company waive the right to resolve any such dispute through a trial by jury or judge or administrative proceeding**. In addition, all claims, disputes, or causes of action under this provision, whether by you or the Company, must be brought in an individual capacity, and shall not be brought as a plaintiff (or claimant) or class member in any purported class or representative proceeding, nor joined or consolidated with the claims of any other person or entity. The Arbitrator may not consolidate the claims of more than one person or entity, and may not preside over any form of representative or class proceeding. To the extent that the preceding sentences regarding class claims or proceedings are found to violate applicable law or are otherwise found unenforceable, any claim(s) alleged or brought on behalf of a class shall proceed in a court of law rather than by arbitration. The Company acknowledges that you will have the right to be represented by legal counsel at any arbitration proceeding. Questions of whether a claim is subject to arbitration under this agreement) shall be decided by the arbitrator. Likewise, procedural questions which grow out of the dispute and bear on the final disposition are also matters for the arbitrator. The arbitrator shall: (a) have the authority to compel adequate discovery for the resolution of the dispute and to award such relief as would otherwise be permitted by law; (b) issue a written arbitration decision, to include the arbitrator's essential findings and conclusions and a statement of the award; and (c) be authorized to award any or all remedies that you or the Company would be entitled to seek in a court of law. The Company shall pay for JAMS' arbitration fees. Each party is responsible for its own attorneys' fees. Notwithstanding the

preceding, the arbitrator is authorized to allocate attorneys' fees and expenses and interest to either party considering in part whether the actions or lack of action by either party caused delay or additional costs. Nothing in this letter agreement is intended to prevent either you or the Company from obtaining injunctive relief in court to prevent irreparable harm pending the conclusion of any such arbitration. Any awards or orders in such arbitrations may be entered and enforced as judgments in the federal and state courts of any competent jurisdiction.

To indicate your acceptance of the Company's offer, please sign and date this letter in the space provided below and the CIIA. A duplicate original is enclosed for your records. This letter, along with the CIIA and any other agreements relating to proprietary rights between you and the Company, set forth the terms of your employment with the Company and supersede any prior representations or agreements, including, but not limited to, any representations made during your interviews or negotiations, whether written or oral. This letter, including, but not limited to, the at-will employment provision set forth herein, may not be modified or amended except by a written agreement signed by the Chief Executive Officer of the Company and you.

Sincerely,

/s/ Mai-Britt Zocca

Mai-Britt Zocca, CEO

Acknowledged and accepted:

/s/ Amy Sullivan

Amy Sullivan

Date: October 3, 2022

Enclosures
Employee Confidential Information and Inventions Assignment Agreement

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Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the following Registration Statements:

(1) Registration Statement (Form S-3 No. 333-269569) of IO Biotech, Inc.,

(2) Registration Statement (Form S-8 No. 333-262587) pertaining to the 2021 Equity and Incentive Plan and 2021 Employee Stock Purchase Plan of IO Biotech, Inc., and

(3) Registration Statement (Form S-8 No. 333-269597) pertaining to the IO Biotech, Inc. 2021 Equity and Incentive Plan; Plan, and

(4) Registration statement (Form S-3 No. 333-274267) of IO Biotech, Inc.;

of our report dated March 14, 2023 March 5, 2024, with respect to the consolidated financial statements of IO Biotech, Inc. included in this Annual Report (Form 10-K) of IO Biotech, Inc. for the year ended December 31, 2022 December 31, 2023.

/s/ EY Godkendt Revisionspartnerselskab

Copenhagen, Denmark

March 14, 2023 5, 2024

Exhibit 31.1

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Mai-Britt Zocca, certify that:

1. I have reviewed this Annual Report on Form 10-K of IO Biotech, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 14, 2023 March 5, 2024

By: /s/ Mai-Britt Zocca

Mai-Britt Zocca, Ph.D.
Chief Executive Officer and Director
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Amy Sullivan, certify that:

1. I have reviewed this Annual Report on Form 10-K of IO Biotech, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 14, 2023 March 5, 2024

By: /s/ Amy Sullivan, M.B.A.

Amy Sullivan, M.B.A.
Chief Financial Officer
(Principal Financial Officer)

Exhibit 31.3

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Brian Burkavage, certify that:

1. I have reviewed this Annual Report on Form 10-K of IO Biotech, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 14, 2023

By: /s/ Brian Burkavage

Brian Burkavage
Chief Accounting Officer
(Principal Accounting Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of IO Biotech, Inc. (the “Company”) on Form 10-K for the period ending December 31, 2022 December 31, 2023 as filed with the Securities and Exchange Commission on the date hereof (the “Report”), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002,

that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: March 14, 2023 March 5, 2024

By: /s/ Mai-Britt Zocca

Mai-Britt Zocca, Ph.D.
Chief Executive Officer and Director
(Principal Executive Officer)

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of IO Biotech, Inc. (the "Company") on Form 10-K for the period ending December 31, 2022 December 31, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: March 14, 2023 March 5, 2024

By: /s/ Amy Sullivan, M.B.A.

Amy Sullivan, M.B.A.
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.3 97.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO IO BIOTECH, INC.
SECTION 906 POLICY ON RECOUPMENT OF THE SARBANES-OXLEY ACT OF 2002 INCENTIVE COMPENSATION
In connection with

Introduction

The Compensation Committee (the "Compensation Committee") of the Annual Report Board of Directors (the "Board") of IO Biotech, Inc. (the "Company" "Company") has adopted this Policy on Form 10-K Recoupment of Incentive Compensation (this "Policy"), which provides for the period ending December 31, 2022 as filed recoupment of compensation in certain circumstances in the event of a restatement of financial results by the Company. This Policy shall be interpreted to comply with the requirements of U.S. Securities and Exchange Commission on the date hereof (the "Report" ("SEC"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 rules and Nasdaq Stock Market ("Nasdaq") listing standards implementing Section 954 of the Sarbanes-Oxley Dodd-Frank Wall Street Reform and Consumer Protection Act of 2002, that: 2010 (the "Dodd-Frank Act") and, to the extent this Policy is in any manner deemed inconsistent with such rules, this Policy shall be treated as retroactively amended to be compliant with such rules.

(1)

Administration

This Policy shall be administered by the Compensation Committee. Any determinations made by the Compensation Committee shall be final and binding on all affected individuals. The Report fully complies Compensation Committee is authorized to interpret and construe this Policy and to make all determinations necessary, appropriate or advisable for the administration of this Policy, in all cases consistent with the requirements Dodd-Frank Act. The Board or Compensation Committee may amend this Policy from time to time in its discretion.

Covered Executives

This Policy applies to any current or former "executive officer," within the meaning of section 13(a) or 15(d) of Rule 10D-1 under the Securities Exchange Act of 1934; 1934, as amended, of the Company or a subsidiary of the Company (each such individual, an "Executive"). This Policy shall be binding and

enforceable against all Executives and their beneficiaries, executors, administrators, and other legal representatives.

Recoupment Upon Financial Restatement

(2)

The information contained If the C
requirement under the securities
previously issued financial statem
uncorrected in the current period
as promptly as reasonably p

No-Fault Recovery

Recoupment under this Poli
accounting errors that contr

Compensation Subject to

This Policy applies to all ma
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financial statements, and ar

measures, whether or not p
total shareholder return ("TS
granted to the Executive ("In
occurrence of operations no
solely at the discretion of th
subject to this Policy.

In the event of a Financial R
Executive during the Recov
withheld, over (ii) the Incent
restated financial informatio
completed fiscal years imme
in accordance with the last s
forth in Section 5608(b)(i)(D
the earlier to occur of (A) th
concludes, or reasonably sh
regulator, or other legally au

For Incentive-Based Compe
mathematical recalculation
amount to be recovered bas
Incentive-Based Compensa
Incentive-Based Compensa
reporting measure was attai
end of that period.

The Company may use any
Compensation, including bu

forfeiting any amounts that t

No Indemnification

The Company shall not inde
Executive under this Policy.

Exceptions

The compensation recoupe
service as an Executive or (
Based Compensation in que
not to seek recovery from a
impracticable because (A) t
having made a reasonable a

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erroneously awarded Incent
would violate the home cou
applicable jurisdiction that is
tax-qualified retirement plan
amended, and the regulatio

Other Remedies Not Precl

Date: March 14, 2023

The exercise by the Compe
pursuant to this Policy shall
rights or remedies that the C
Compensation Committee r
Executive subject to this Po

Effective Date and Applica

This Policy has been adopte
that is received by an Execu
