Risk Factors Comparison 2025-03-20 to 2024-03-21 Form: 10-K

Legend: **New Text** ~~Removed Text~~ Unchanged Text Moved Text Section

Risks Related to Our Business and Industry • We have never been profitable and may never achieve or maintain profitability. • ~~There is substantial doubt regarding our ability to continue as a going concern.~~ We will need to raise additional funding, which may not be available on acceptable terms, or at all. Failure to obtain this necessary capital when needed may force us to delay, limit or terminate our product development efforts or other operations. • If we are unable to raise substantial additional capital on acceptable terms, or at all, we may be forced to delay, reduce or eliminate some or all of our research programs, product development activities and commercialization efforts. • We **may not be able to successfully integrate recent and future acquisitions. • We** have a limited operating history, which makes it difficult to evaluate our current business and future prospects and may increase the risk of your investment. • We may expend our limited resources pursuing particular research programs or product candidates that may be less successful or profitable than other programs or product candidates. • Fluctuating foreign exchange rates could increase our operating expenses and adversely affect our **results of operations. • Inflation could adversely affect our business and** results of operations. Risks Related to Our Product Candidates • Our business is dependent on the successful development, regulatory approval and commercialization of our therapeutic product ~~candidate~~ **candidates** , CTIM- 76, **CT- 95 and CT- 202,** which ~~is~~ **are** in the early stages of development. • Results of preclinical studies, early clinical trials or analyses may not be indicative of results obtained in later trials. • Interim " top- line " and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data becomes available and are subject to audit and verification procedures that could result in material changes in the final data. • Any product candidate may cause serious adverse events or undesirable side effects, which may delay or prevent marketing approval, or, if approved, require it to be taken off the market, require it to include safety warnings or otherwise limit its sales **. • We may find it difficult to enroll patients in our clinical trials. If we encounter difficulties or delays enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected** . • The success of our business depends primarily upon our ability to identify, develop and commercialize products using our proprietary technologies. Risks Related to Our Organization, Structure and Operations • Our reliance on a central team consisting of a limited number of employees and consultants who provide various administrative, research and development, and other services across our organization presents operational challenges that may adversely affect our business. • Our future success depends on our ability to retain our executive officers and other key executives and to attract, retain and motivate qualified personnel. Risks Related to Our Reliance on Third Parties • We expect to, and do, depend on collaborations with third parties for certain research, development and commercialization activities, and to rely on third parties to conduct, supervise and monitor our clinical trials and some aspects of our research and preclinical testing, as well as for the manufacturing process of ~~product~~ **iiproduct** candidates. If any such collaborations or services by such third parties are not successful or not performed in a satisfactory manner, it may harm our business and prospects, and we may not be able to obtain regulatory approval or commercialize product candidates, or such approval or commercialization may be delayed, and our business may be substantially harmed. • We may become involved in disagreements or disputes with our licensees, licensors and other counterparties relating to the development and / or commercialization of our current or past product ~~iicandidates~~ -- **candidates** , which may be time consuming, costly and could harm our efforts to develop our current or future product candidates. Risks Related to Government Regulation • The FDA regulatory approval process is lengthy and time- consuming, and we may experience significant delays in the clinical development and regulatory approval of our current and any future product candidates. • We expect that CTIM- 76 **, CT- 95 and CT- 202** will be regulated as biological products, or biologics, and therefore they may be subject to competition ~~sooner than anticipated~~ **from biosimilar applicants** . • The FDA may disagree with our regulatory plan and we may fail to obtain regulatory approval of any product candidate. • Obtaining and maintaining regulatory approval of a product candidate in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of such product candidate in other jurisdictions. • Even if we obtain regulatory approval of a product candidate, the product may not gain market acceptance among physicians, patients, hospitals, cancer treatment centers and others in the medical community. • Coverage and reimbursement may be limited or unavailable in certain market segments for a product candidate, which could make it difficult for us to sell such product candidate, if approved, profitably. Risks Related to Intellectual Property • Patents and patent applications involve highly complex legal and factual questions, which, if determined adversely to us, could negatively impact our business position. • Third parties may assert claims against us alleging infringement of their patents and proprietary rights, or we may need to become involved in lawsuits to defend or enforce our patents, either of which could result in substantial costs or loss of productivity, delay or prevent the development and commercialization of our current and any future product candidates, prohibit our use of proprietary technology or sale of potential products or put our patents and other proprietary rights at risk. • Our ability to compete effectively in our markets may decline if we do not adequately protect our proprietary rights, and our proprietary rights do not necessarily address all potential threats to our competitive advantages. • If we fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business. • We may not be able to protect our intellectual property rights throughout the world. Risks Related to the Market for Our Common Stock • Our common stock may be volatile or may decline regardless of our operating performance. • We may not be able to **regain and** maintain compliance with the continued listing requirements of The Nasdaq Stock Market. • We may issue debt and equity securities, which are senior to our common stock as to distributions and in liquidation, which could

materially adversely affect the market price of our common stock. • We may fail to maintain effective internal control over financial reporting and effective disclosure controls and procedures. If we fail to remediate any material weaknesses, we may not be able to report our financial results accurately or to prevent fraud, which could materially adversely affect the market price of our common stock. • Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates. iii NOTE REGARDING FORWARD- LOOKING STATEMENTS This Form 10- K contains " forward- looking statements " within the meaning of the Private Securities Litigation Reform Act of 1995. These statements are based on our management' s beliefs and assumptions and on information currently available to us. All statements other than statements of historical facts are forward- looking statements. The forward- looking statements are contained principally in, but not limited to, the sections entitled " Risk Factors, " " Management' s Discussion and Analysis of Financial Condition and Results of Operations " and " Business. " These statements relate to future events or to our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied by these forward- looking statements. Forward- looking statements include, but are not limited to, statements about: • the ability of our preclinical studies and clinical trials to demonstrate safety and efficacy of our product candidates, and other positive results; • the timing, progress and results of preclinical studies and clinical trials for CTIM- 76 **, CT- 95, CT- 202** and other product candidates we may develop, including statements regarding the timing of initiation and completion of studies or trials and related preparatory work, the period during which the results of the trials will become available, and our research and development programs; • the timing, scope and likelihood of U. S. and foreign regulatory filings and approvals, including timing of Investigational New Drug **(" IND ")** applications and final U. S. Food and Drug Administration (" FDA ") approval **, as well as similar applications and approvals in foreign jurisdictions,** of CTIM- 76 **, CT- 95, CT- 202** and any other future product candidates; • our ability to develop and advance CTIM- 76 **, CT- 95, CT- 202** and any other future product candidates, and successfully complete clinical studies; • our manufacturing, commercialization, and marketing capabilities, implementations thereof, and strategy; • our plans relating to commercializing our product candidates, if approved, including the geographic areas of focus, sales strategy, and our ability to grow a sales team; • our intellectual property position, including the scope of protection we are able to establish and maintain for intellectual property rights covering CTIM- 76 **, CT- 95, CT- 202** , and other product candidates we may develop, including the extensions of existing patent terms where available, the validity of intellectual property rights held by third parties, and our ability not to infringe, misappropriate or otherwise violate any third- party intellectual property rights; • any disagreements or disputes with our licensees, licensors and other counterparties relating to the development and / or commercialization of our current or past product candidates, which may be time consuming, costly and could harm our efforts to develop our current or future product candidates; • the impact of economic uncertainties on our business and operations, including clinical trials, manufacturing suppliers, collaborators, use of contract research organizations and employees; • the need to hire additional personnel and our ability to attract and retain such personnel; • the size of the market opportunity for our product candidates, including our estimates of the number of patients who suffer from the diseases we are targeting; • our competitive position and the success of competing therapies that are or may become available; • the beneficial characteristics, safety, efficacy and therapeutic effects of our product candidates; • our ability to obtain and maintain regulatory approval of our product candidates; • our plans relating to the further development of our product candidates, including additional indications we may pursue; • existing regulations and regulatory developments in the United States, Europe and other jurisdictions; • our continued reliance on third parties to conduct and support clinical trials of our product candidates, and for the manufacture of our product candidates for preclinical studies and clinical trials; • our ability to obtain, and negotiate favorable terms of, collaboration, licensing or other arrangements that may be necessary or desirable to develop, manufacture or commercialize our product candidates; • the pricing and reimbursement of CTIM- 76 **, CT- 95, CT- 202** and other product candidates we may develop, if approved; • the rate and degree of market acceptance and clinical utility of CTIM- 76 **, CT- 95, CT- 202** and other product candidates we may develop; • our estimates regarding expenses, future revenue, capital requirements and needs for additional financing; • our current plans to seek additional capital in the future through equity and / or debt financings, partnerships, collaborations, licensing agreements or other strategic arrangements, or other sources and the availability of such future sources of capital; • our financial performance; • the period over which we estimate our existing cash and cash equivalents will be sufficient to fund our future operating expenses and capital expenditure requirements; • the impact of laws and regulations; • our expectations regarding the period during which we will qualify as an emerging growth company under the JOBS Act; • our anticipated use of our existing cash and cash equivalents; and • other risks and uncertainties, including those listed under the caption " Risk Factors ". In some cases, you can identify forward- looking statements by terms such as " may, " " could, " " will, " " should, " " would, " " expect, " " plan, " " intend, " " anticipate, " " believe, " " estimate, " " predict, " " potential, " " project " or " continue " or the negative of these terms or other comparable terminology. These statements are only predictions. You should not place undue reliance on forward- looking statements because they involve known and unknown risks, uncertainties and other factors, which are, in some cases, beyond our control and which could materially affect results. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under the heading " Risk Factors " and elsewhere in this Form 10- K. If one or more of these risks or uncertainties occur, or if our underlying assumptions prove to be incorrect, actual events or results may vary significantly from those implied or projected by the forward- looking statements. No forward- looking statement is a guarantee of future performance. As a result, you should not place undue reliance on forward- looking statements. This Form 10- K also contains certain data and information which we obtained from various government and private publications or third parties. Although we believe that the publications, information, data and reports are reliable, we have not independently verified the data. Statistical data in these publications includes projections that are based on a number of assumptions. If any one or more of the assumptions underlying the market data is later found to be incorrect, actual results may

differ from the projections based on these assumptions. Scientific and clinical data presented herein are – by definition prior to completion of the clinical trial and a clinical study report – preliminary in nature and subject to further quality checks including customary source data verification. The forward- looking statements made in this Form 10- K relate only to events or information as of the date of the Form 10- K (or any earlier date indicated in such statement). Although we are a public company and have ongoing disclosure obligations under United States federal securities laws, we do not intend to update or otherwise revise the forward- looking statements in this Form 10- K, whether as a result of new information, future events or otherwise. MARKET, INDUSTRY AND OTHER DATA This Annual Report on Form 10- K contains estimates, projections, market research and other information concerning our industry, our business, markets for our product candidates, the size of those markets, and the prevalence of certain medical conditions. Unless otherwise expressly stated, we obtain this information from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data and similar sources as well as from our own internal estimates and research and from publications, research, surveys and studies conducted by third parties on our behalf. Information that is based on estimates, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances that are reflected in this information. As a result, you are cautioned not to give undue weight to such information. **vii** PART I. Item 1. Business Overview We are a **clinical- stage** biopharmaceutical company advancing ~~medicines~~ **T cell engaging (" TCE ") bispecific antibodies (" bsAb ")** for solid tumors. **We are building an innovative portfolio of TCE bispecific therapeutics** ~~Profound advancements in oncology drug development have expanded the treatment options available to cancer patients~~ , **including** ~~yet the need for additional treatment options exists. Our preclinical program,~~ CTIM- 76, **a** ~~is an anti-~~ Claudin 6 (" CLDN6 ") x ~~anti-~~ CD3 ~~bispecific antibody~~ **TCE, CT- 95, a Mesothelin** (" ~~bsAb~~ **MSLN** ") **x CD3 TCE, and CT- 202, a Nectin cell adhesion protein 4 (" Nectin- 4 ") x CD3 TCE. Our pipeline is shown below: CTIM- 76 is a CLDN6 x CD3 TCE** that is intended to redirect T- cell- mediated lysis toward malignant cells expressing CLDN6. CLDN6 is a tight junction membrane protein target expressed in multiple solid tumors and absent from or expressed at low levels in healthy adult tissues. **IND- enabling studies on** CTIM- 76 ~~investigational new~~ **have been completed. On May 2, 2024, we announced the U. S. Food and** ~~drug~~ **Drug Administration** (**the** " ~~IND~~ **FDA** ") **cleared our IND application to support the initiation of a Phase 1 dose escalation and expansion trial of CTIM** - **76 in patients** ~~enabling studies are ongoing,~~ with **CLDN6- positive gynecologic** ~~an~~ **and testicular cancers** ~~IND filing to support human clinical trials expected by the end of March 2024~~ . We ~~plan to initiate a~~ **dosed the first patient in our CTIM- 76** Phase 1 trial **in January 2025** ~~to focus on CLDN6- positive gynecologic and testicular cancers upon receiving IND clearance from the FDA~~ . We expect to **share initial data** ~~have sufficient cash and cash equivalents to fund our operations into late 2024. We will require additional funding~~ for ~~our planned~~ **the CTIM- 76** Phase 1 trial ~~,~~ **in** ~~other~~ -- **the** ~~research~~ **first half of 2026. CT- 95 is** ~~and~~ - **an** ~~development expenditures, and general and administrative expenses~~ **MSLN x CD3 TCE that is intended to redirect T- cell- mediated lysis toward malignant cells expressing MSLN** . ~~On March 22,~~ **MSLN is a membrane protein overexpressed in approximately 30 % of cancers. We anticipate dosing the first patient in the CT- 95 Phase 1 trial in the second quarter of 2025. We expect to share initial data for the CT- 95 Phase 1 trial in the middle of 2026. CT-** ~~2023~~ - **202 is** ~~, we announced~~ a ~~portfolio prioritization~~ **Nectin- 4 x CD3 TCE that targets Nectin- 4, a cell surface protein that is highly** and ~~capital allocation strategy~~ **frequently overexpressed in a variety of solid tumors** , including **bladder, colorectal, lung** ~~discontinuing the development of ONA- XR~~ and **breast** ~~focusing on the development of CTIM- 76~~ . ~~Based upon the challenging market conditions~~ **Nectin- 4 is a clinically validated target** for ~~emerging companies~~ **cancer therapy using a traditional antibody- drug conjugate (" ADC ")** , **but it is also associated with certain adverse events, including neuropathy and rash. CT- 202 is a pH- dependent TCE that is designed to be preferentially active within** the ~~increasingly competitive landscape~~ **tumor microenvironment. We expect to file an IND application** for **CT- 202 in** ~~breast cancer treatments, recent study findings, and other~~ -- **the middle of 2026** ~~factors, we decided to cease development and explore strategic options for ONA- XR. As a result, we no longer primarily focus on female cancers~~ . Beyond these product candidates, we continue to evaluate opportunities to expand our pipeline. We believe our team and capabilities position us to be a leader in developing novel therapies targeting solid tumors. We retain full worldwide development and commercialization rights to certain CTIM- 76 patents in the field of bispecific antibodies **, full worldwide development and commercialization rights to CT- 95 patents, and full worldwide development and commercialization rights to certain CT- 202 patents. Our Strategy Our goal is to deliver safe and effective selective cancer therapies for patient populations with significant unmet medical needs. Key elements of our strategy include: • Rapidly advance our CTIM- 76 and CT- 95 clinical programs through Phase 1 proof of concept. We are currently evaluating CTIM- 76 in a Phase 1 clinical trial and plan to provide preliminary data in the first half of 2026. Additionally, we anticipate dosing the first patient in the CT- 95 Phase 1 trial in the second quarter of 2025 and plan to provide preliminary data in the middle of 2026. • Rapidly advance our third program, CT- 202, through preclinical development. We are currently advancing our CT- 202 program through Good Manufacturing Practices (" GMP ") manufacturing and IND enablement. • Seek opportunities to expand our pipeline of selective cancer drug candidates and targets. We intend to continue to seek opportunities to expand our TCE pipeline for solid tumors. If we identify targets that we deem to have high potential to address unmet medical needs, we may develop, in- license or acquire assets with therapeutic potential against those identified selective cancer targets. • Evaluate strategic opportunities to potentially accelerate development timelines and enhance the commercial potential of our product candidates globally. We intend to leverage our TCE expertise to advance a novel pipeline. We plan to commercialize our product candidates in key markets, either alone or with strategic partners, and seek to maximize the worldwide commercial potential of our programs** . Our Product Pipeline and Development CLDN6xCD3 **TCE** ~~bispecific antibody~~ program: CTIM- 76 Our ~~preclinical~~ --- **clinical** product candidate, CTIM- 76, is **a CLDN6** ~~an anti- Claudin 6~~ x ~~anti-~~ CD3 **TCE** ~~(" CLDN6xCD3 ") bispecific antibody~~ that is intended to redirect T- cell- mediated lysis toward malignant cells

expressing CLDN6. CLDN6 is a tight junction membrane protein target that has high prevalence across many solid tumors and is absent from or expressed at low levels in healthy adult tissues. ~~Due to~~ **We believe CTIM- 76 has** the ~~broad prevalence of~~ **potential to be a differentiated** CLDN6 **product candidate, due** in ~~solid~~ **part to: (i) its high selectivity for CLDN6 over Claudin 3 (“ CLDN3 ”), Claudin 4 (“ CLDN4 ”), and Claudin 9 (“ CLDN9 ”); and (ii) its potential ability to target** tumors **with low** , ~~we~~ **medium or high levels of CLDN6 expression** , ~~along~~ **which could potentially result in a broader target population and greater commercial opportunity compared** with other **approaches** ~~pharmaceutical companies, including but not limited, TORL Biotherapeutics (“ TORL ”), BioNTech SE (“ BioNTech ”), Xencor, Inc~~ . **Structure** ~~(“ Xencor ”)~~ and **Mechanism of Action** ~~Amgen Inc. (“ Amgen ”), are developing anti-~~ CLDN6 ~~antibody- drug conjugates~~ **is an oncofetal protein that is normally present at higher levels during embryonic development. In normal** , ~~cell therapies~~ **adult tissue** , **CLDN6 is turned off** or ~~bispecific antibodies~~ **has very low levels of expression due to epigenetic silencing. CLDN6 is thought to be reactivated by some cancers to adopt a more embryonic phenotype through the process of dedifferentiation** . The structural complexity of CLDN6 and its similarity to other Claudin proteins expressed on healthy tissue, particularly ~~Claudin 3 (“~~ CLDN3 ~~”)~~ , ~~Claudin 4 (“~~ CLDN4 ~~”)~~ , and ~~Claudin 9 (“~~ CLDN9 ~~”)~~ , make selectivity a key development challenge that must be addressed by CLDN6- targeting assets in development. **The figure below indicates that CTIM- 76 is a highly selective and potent CLDN6 x CD3 TCE. Market Opportunity There is a significant global opportunity for the treatment of patients with tumors expressing CLDN6. CLDN6 is overexpressed in several cancers with significant unmet needs, including ovarian, non- small cell lung, colon, endometrial, breast, sarcoma and testicular, with expression being highest in ovarian, endometrial, and testicular adenocarcinomas. Estimated incidence information for annual new cancer cases in the United States and CLDN6 expression rates for certain cancers with significant unmet needs are shown below. We estimate that greater than 50, 000 patients per year in the United States have CLDN6- positive relapse / refractory (“ R / R ”) disease. Initial indications of interest are based on: (i) CLDN6 prevalence; (ii) patient population size; (iii) observed clinical responses; and (iv) potential for accelerated development. Selected Cancer indicationsIncidence (US Only) R / R IncidenceCLDN6 PositiveCLDN6Med / HighPatient PopulationBased on R / R IncidenceEndometrial65, 90014, 00051 % 122 % 17, 140Ovarian19, 90012, 80044 % 125 % 15, 632Testicular9, 91040094 % 190 % 1376Non- Small Cell Lung201, 229110, 65326 % 16 % 128, 769Colon152, 81053, 01040 % 20 % 221, 204Breast290, 60043, 80040 % 20 % 29, 417Sarcoma17, 10012, 39020 % 210 % 22, 478Gastric26, 38011, 0909 % 17 % 1998 1 Context internal data; 2 Mackensen, Nature Medicine, 2023. Incidences based on public estimates; R / R or last-line patient population approximated by annual mortality; CLDN6 target prevalence is based on IHC or RNAseq from published reports. Patient population derived from midpoint of CLDN6 positive population multiplied by R / R incident population. Clinical Validation of the Target and Potential for Broader Patient Population Based on clinical data reported for other therapeutic agents targeting CLDN6, including BioNTech (BNT211), TORL (TORL- 1- 23), and Daiichi Sankyo (DS9606a), in various phases of clinical development, including ADC and CAR T- cell approaches, we believe this target has been clinically validated. Whereas both ADC and CAR T- cell anti- CLDN6 approaches have required a substantial portion of tumor cells with high expression of CLDN6 for anti- tumor activity, we believe a T cell engager approach could potentially target tumors with varying levels of CLDN6 expression, including tumors with low levels of expression. Therefore, CTIM- 76 could potentially capture a broader patient population and greater commercial opportunity. Clinical Development Plan We have an active IND for CTIM- 76 with the FDA, and in January 2025, we announced that the first patient had been dosed in the Phase 1 clinical trial of CTIM- 76, which is a dose escalation and expansion trial in patients with solid tumors likely to express CLDN6. In the dose escalation part of our Phase 1 trial, we expect to enroll patients with advanced unresectable or metastatic ovarian, endometrial or testicular cancer in increasing dose levels. The primary objective in dose escalation will be to evaluate the safety and tolerability of CTIM- 76. In the expansion part of our Phase 1 trial, we plan to evaluate two doses in a single cancer type based upon dose escalation data. The primary objective in expansion will be to evaluate preliminary anti- tumor activity of CTIM- 76 and to select a dose for future trials. CLDN6 expression will be required for enrollment in our Phase 1 trial for patients with ovarian and endometrial cancer. Due to high CLDN6 expression, prospective screening for testicular cancer will not be required. Mesothelin x CD3 TCE program: CT- 95 Our clinical product candidate, CT- 95, is an MSLN x CD3 TCE that is intended to redirect T- cell- mediated lysis toward malignant cells expressing MSLN. MSLN is a membrane protein overexpressed in approximately 30 % of cancers. One challenge in developing MSLN- targeted therapies has been the presence of MSLN fragments, also referred to as shed or soluble MSLN (“ sMSLN ”), found in both blood and the tumor microenvironment that can serve as a decoy or sink for MSLN- targeting antibodies. CT- 95 is a fully humanized bispecific T cell engager that has a moderate affinity but high avidity for membrane- bound MSLN, minimizing the impact of the sMSLN. We believe CT- 95 has the potential to be a differentiated MSLN product candidate, due in part to: (i) its ability to bind to the membrane- proximal side of MSLN, which has been shown to increase potency compared to a historic program from Harpoon Therapeutics (HPN536), potentially driving improved outcomes for patients; (ii) avidity enhancement to improve CT- 95 residence in the tumor microenvironment and minimize the risk of cytokine release syndrome; and (iii) its potential ability to target tumors with low, medium or high levels of MSLN expression, which could potentially result in a broader target population and greater commercial opportunity compared with non- TCE approaches. On July 9, 2024, we entered into an asset purchase agreement (the “ Asset Purchase Agreement ”) pursuant to which we acquired CT- 95 (formerly known as LNK- 101), from Link (assignment for the benefit of creditors), LLC (“ Link ”), which succeeded to the assets of Link Immunotherapeutics Inc. The FDA previously cleared the IND application for CT- 95. Pursuant to the Asset Purchase Agreement, we purchased the assets of Link associated with CT- 95, including patent rights, know- how, regulatory filings, and inventory of drug substance and drug product (the “ Transferred Assets ”), on an “ as is ” and “ where is ” basis. CT- 95 patents are**

currently being prosecuted and / or maintained in the United States, Europe, Canada, Australia, Japan and Taiwan. We also assumed certain liabilities relating to the Transferred Assets. In consideration of the Transferred Assets, we made a one- time payment to Link of $ 3. 75 million. MSLN is bound to tumor cells via a glycosylphosphatidylinositol (“ GPI ”) linker. Like many GPI- anchored proteins, MSLN can be cut into smaller fragments. The MSLN gene encodes a precursor that is cleaved into two products: a soluble N- terminal protein called megakaryocyte potentiating factor (MPF), and a membrane- bound fragment called full length mesothelin (“ FL- MSLN ”). FL- MSLN can then be further cleaved into even smaller sMSLN fragments. sMSLN serves as a competitive sink, preventing antibodies from binding to the tumor, which can lead to suboptimal drug exposure and efficacy. CT- 95 was designed to overcome the sMSLN sink through binding to membrane- proximal MSLN epitope and avidity enhancement. CT- 95 exhibits moderate affinity for membrane- proximal MSLN but cooperative binding through bivalent binding of CT- 95 to two MSLN epitopes results in high avidity binding of CT- 95 to the tumor. This results in a potentially wide therapeutic window due to: (i) limited crosslinking by sMSLN, mitigating off- tumor T cell activation; and (ii) cooperative binding of MSLN on tumor surface to crosslink CD3, thereby activating T cells. The figure below indicates that HPN- 536 (Harpoon Therapeutics) binds to MSLN fragments in a dose proportional manner, limiting therapeutic exposure, whereas CT- 95 does not lose potency in the same OVCAR- 3 cell line model. There is a significant global opportunity for the treatment of patients with tumors expressing MSLN. MSLN is overexpressed in several cancers with significant unmet needs, high grade serous ovarian, non- small cell lung, colon, esophageal, pancreatic carcinoma, endometrial, gastric, and mesothelioma, with expression being highest in high- grade serous ovarian cancer, pancreatic carcinoma, and mesothelioma. Estimated incidence information for annual new cancer cases in the United States and MSLN expression rates for certain cancers with significant unmet needs are shown below. We estimate that greater than 100, 000 patients per year in the United States have mesothelin- positive R / R disease. Initial indications of interest are based on: (i) MSLN prevalence; (ii) patient population size; (iii) observed clinical responses; and (iv) potential for accelerated development. Selected Cancer indicationsIncidence (US Only) R / R IncidenceMSLN PositiveMSLN Med / HighPatient PopulationBased on R / R IncidenceNon- Small Cell Lung201, 229110, 65355 % 36 % 60, 859Pancreatic66, 44051, 75080 % 61 % 41, 400Ovarian19, 90012, 80090 % 80 % 11, 520Mesothelioma3, 0002, 50070 % 60 % 1, 750Colon152, 81053, 01041 % 17 % 21, 734Esophageal22, 37016, 13041 % 26 % 6, 613Endometrial65, 90014, 00045 % 23 % 6, 300Gastric26, 38011, 09049 % 23 % 5, 434Breast (TNBC) 62, 05415, 50030 % 18 % 4, 650Cervical13, 8204, 36042 % 21 % 1, 831 Incidences based on public estimates; R / R or last- line patient population approximated by annual mortality; MSLN target prevalence is based on Simon et al, Biomedicines, 2021. Patient population derived from MSLN positive population multiplied by R / R incident population. Based on clinical data reported for other therapeutic agents targeting MSLN, including RemeGen Biosciences (RC88) and TCR2 Therapeutics (gavocabtagene autoleucel), in various phases of clinical development, including ADC and CAR T- cell approaches, we believe this target has been clinically validated. Whereas both ADC and CAR T- cell anti- MSLN approaches have required a substantial portion of tumor cells with high expression of MSLN for anti- tumor activity, we believe a T cell engager approach could potentially target tumors with varying levels of MSLN expression, including tumors with low levels of expression. Therefore, MSLN could potentially capture a broader patient population and greater commercial opportunity. We have an active IND for CT- 95 with the FDA. We anticipate dosing the first patient in the CT- 95 Phase 1 trial in the second quarter of 2025, which is a dose escalation trial in patients with solid tumors likely to express MSLN. We expect to enroll patients with advanced unresectable or metastatic high grade serous ovarian cancer, pancreatic carcinoma, and mesothelioma. The primary objective in dose escalation will be to evaluate the safety and tolerability of CT- 95. Expression of MSLN will not be required for enrollment in our Phase 1 trial; tumor tissue samples will be collected for retrospective biomarker assessment of MSLN expression by immunohistochemistry (“ IHC ”). Nectin- 4 x CD3 TCE program: CT- 202 Our preclinical product candidate, CT- 202, targets Nectin- 4, which is highly and frequently overexpressed in a variety of cancers. Nectin- 4 is a clinically- validated target for cancer therapy using a traditional antibody- drug conjugate, but it is also associated with certain adverse events, including neuropathy and rash. CT- 202 is a pH- dependent TCE that is designed to be preferentially active within the acidic tumor microenvironment. On September 23, 2024, we entered into a license agreement (the “ BioAtla License Agreement ”) with BioAtla, Inc. (" BioAtla"), pursuant to which we obtained an exclusive, worldwide license to develop, manufacture and commercialize two licensed antibodies (the “ BioAtla Assets ”), including BA3362 (renamed by the Company as CT- 202), BioAtla’ s Nectin- 4 x CD3 TCE. As partial consideration for the exclusive license under the BioAtla License Agreement, we made an upfront payment of $ 11. 0 million, and BioAtla is eligible to receive up to $ 122. 5 million in additional milestone payments based upon the achievement of specified pre- clinical, clinical, development and commercial milestones, as well as tiered mid- single digit to low double- digit royalties on future net sales for products containing the BioAtla Assets, subject to standard reductions. We believe CT- 202 has the potential to be a differentiated Nectin- 4 product candidate, due in part to: (i) its ability to preferentially bind to Nectin- 4 and CD3 in the low pH environment of tumor relative to pH neutral normal tissue, which has the potential to reduce the risk of dermatologic side effects associated with Nectin- 4 expression in the skin; (ii) avidity enhancement to improve CT- 202 residence in the tumor microenvironment and minimize the risk of cytokine release syndrome; and (iii) its potential ability to target tumors with low, medium or high levels of Nectin- 4 expression, which could potentially result in a broader target population and greater commercial opportunity compared with non- TCE approaches. CT- 202 incorporates logic gating through pH dependence and avidity enhancement which is intended to spare Nectin- 4 in normal tissue. Because of its expression in healthy epidermal keratinocytes, sweat glands, and hair follicles, Nectin- 4 targeted treatments are often associated with dermatological side effects. CT- 202 incorporates pH dependent binding to both Nectin- 4 and CD3 to minimize binding to healthy tissues and maximize binding and T cell activation within the

tumor microenvironment. CT- 202 is avidity optimized to mitigate cytokine release syndrome risk. Cooperative Nectin- 4 binding through bivalent binding to the tumor cell surface is intended to reduce T cell crosslinking in the absence of target. Steric hindrance of CD3 binding by Fc domain prevents T cell crosslinking by single CT- 202 molecules. The figure below indicates our two- pronged approach for CT- 202 to overcome Nectin- 4 expression in the skin and to generate robust antitumor responses while minimizing the risk of cytokine release syndrome. There is a significant global opportunity for the treatment of patients with tumors expressing Nectin- 4. Nectin- 4 is overexpressed in several cancers with significant unmet needs, including bladder (urothelial), non- small cell lung, pancreatic, head and neck, esophageal, colorectal, gastric, and triple negative breast cancer (" TNBC "), with expression being highest in bladder, colorectal, and TNBC. Estimated incidence information for annual new cancer cases in the United States and Nectin- 4 expression rates for certain cancers with significant unmet needs are shown below. We estimate that greater than 125, 000 patients per year in the United States have Nectin- 4- positive R / R disease. Initial indications of interest are based on: (i) Nectin- 4 prevalence; (ii) patient population size; and (iii) observed clinical responses. Selected Cancer indicationsIncidence (US Only) R / R IncidenceNectin- 4 PositiveNectin- 4 Med / HighPatient PopulationBased on R / R IncidenceNon- Small Cell Lung201, 229110, 65364 % 130 % 170, 818Colon152, 81053, 01087 % 178 % 146, 119Pancreatic66, 44051, 75071 % 137 % 136, 743Bladder (urothelial) 83, 19020, 00083 % 160 % 116, 600Breast (TNBC) 62, 05415, 50069 % 153 % 110, 695Head and Neck54, 00012, 00059 % 118 % 17, 080Esophageal22, 37016, 13055 % 124 % 28, 872Gastric26, 89012, 00071 % 360 % 38, 520Ovarian19, 90012, 80057 % 42 % 47, 296 Incidences based on public estimates; R / R or last- line patient population approximated by annual mortality; Patient population derived from Nectin- 4 positive population multiplied by R / R incident population. 1 Challita, Can Res, 2016; 2 Zhang, Oncol Lett, 2018; 3 Derycke, Am J Clin Pathol, 2010; 4 Kobecki, Int J Mol Sci, 2023 Based on clinical data reported for other therapeutic agents targeting Nectin- 4, including Pfizer (Padcev ®) and Bicycle (BT8009), including ADC approaches, we believe this target has been clinically validated. Padcev is currently approved for locally advanced or metastatic urothelial carcinoma, which is associated with high levels of Nectin- 4 expression. Whereas ADC Nectin- 4 approaches require a substantial portion of tumor cells with high expression of Nectin- 4 for anti- tumor activity, we believe a TCE approach could potentially target tumors with varying levels of MSLN expression, including tumors with low levels of expression. Therefore, MSLN could potentially capture a broader patient population and greater commercial opportunity. PR antagonist program: ONA- XR Prior to the portfolio prioritization and capital allocation strategy announced on March 22, 2023, we were primarily focused on developing treatments for female cancers. **Based upon the challenging market conditions for emerging companies, the increasingly competitive landscape for breast cancer treatments, recent study findings, and other factors, we decided to cease development and explore strategic options for** ONA- XR ~~was being evaluated in two Phase 2 trials, and one Phase 1b / 2 trial in women with metastatic breast and endometrial cancers. These trials were intended to establish safety, pharmacokinetics, pharmacodynamics, and anti- tumor activity at the recommended Phase 2 dose of ONA- XR to guide potential advancement in Phase 3 development~~. We wound down our ONA- XR clinical trials and development by the end of 2023. ~~Other preclinical programs In addition to CTIM- 76, we are leveraging our knowledge in solid tumors to pursue discovery stage research programs. We continue to evaluate new opportunities to expand our pipeline. Background CLDN6 CLDN6 is an oncofetal tight junction protein involved in the cell- to- cell adhesion of epithelial and endothelial cell sheets. Although epigenetically silenced in healthy adult human tissues, CLDN6 expression has been found across a broad range of cancer tissues and can lead to a poor prognosis. Monoclonal antibody (MAb) discovery against CLDN6 has been encumbered by the high homology of endogenously expressed CLDN9, which varies from CLDN6 by only three amino acids in the extracellular domain. Proposed mechanism of action Rationale for bispecific antibody Cytotoxic T cells are considered to be the most potent effector cells of the immune system. As a consequence, broad T cell activation can lead to significant and sometimes lethal side effects. Therefore, to harness the potential of cytotoxic T cells, therapeutic strategies seek to pair T cell activation with drug targets that are restricted to cancer tissue so as to avoid unwanted toxicity. CLDN6 expression is restricted to various cancer types (i. e., a tumor specific antigen or TSA), making it an ideal target to help T cells recognize and eliminate cancer cells. Recently, a class of bispecific antibodies (TSAxCD3) with a native immunoglobulin format has emerged that can efficiently trigger T- cell- mediated killing of tumor cells by linking a T cell to a tumor cell and activating the CD3 / T cell receptor complex, as shown above. CLDN6 expression in cancer versus normal tissue Source: Cancer RNAseq data from The Cancer Genome Atlas (TCGA); normal tissue RNAseq data from the Genotype- Tissue Expression (GTEx) project. Preclinical data CTIM- 76 is a CLDN6xCD3 bsAb capable of binding to tumor cells expressing CLDN6 and stimulating intra- tumoral T cells by the CD3 arm that is designed to be activated only upon tumor engagement while silent elsewhere. CLDN6 is expressed on multiple solid tumors such as ovarian, endometrial, lung and testicular. As shown below, CTIM- 76 exhibits excellent selectivity and specificity for CLDN6. Preclinical studies of CTIM- 76 show it effectively maintains a strong tumor binding property and anti- tumor activity attributable to a synergistic effect of both CLDN6 binding and CD3 binding while avoiding systemic immunotoxicity commonly seen with CD3 antibodies as a drug class. CTIM- 76 has the potential for convenient dosing and scalable manufacturing to address the significant number of patients who are potentially eligible for CTIM- 76 therapy. An important aspect of CTIM- 76 is the ability of the bispecific to preferentially target CLDN6 over related proteins. There is high sequence homology (~ 95 %) between CLDN6 and CLDN9 in the extracellular loops, making the isolation of a CLDN6- specific antibody challenging. As shown below, CTIM- 76 preferentially targets CLDN6, with minimal activity against CLDN9- expressing cells. Further, no binding was observed to other CLDN family proteins (CLDN3 and CLDN4) that have < 85 % homology in the extracellular loops. Study design: K562 cells stably over- expressing CLDN3, CLDN4, CLDN6, or CLDN9 were co- cultured with human T- cells at an E: T ratio of 10: 1 for 48 hours. Cytotoxicity was determined by luminescence imaging. CTIM- 76 has the potential for a wide therapeutic window, which is the difference between the dose required for the intended therapeutic effect and the dose required to elicit an unwanted side effect. The**

~~therapeutic goal, therefore, is to maximize cancer cell death through selective immune activation. CTIM- 76 was evaluated in preclinical assays to determine the risk of on- / off- target immune system activation. As shown below, preclinical data supports the potential to dose at levels that promote cancer cell killing but have manageable levels of free cytokine production, thereby potentially reducing the risk of cytokine release syndrome. In the assay, cytokine production was evaluated in the exogenous (CLDN6- K562) cell line model at 48 hours. Cytokine production happened well above the concentration of maximal killing (TDCC EC50 = 0. 0004 nM), indicating a potentially wide therapeutic window. Study design: K562 cells stably over- expressing CLDN6 and luciferase were co- cultured with human T cells at an E: T ratio of 10: 1 for 48 hours. To test whether CTIM- 76 had sufficiently strong efficacy and safety to support first- in- human clinical trials, we conducted a series of in vivo experiments. CTIM- 76 was evaluated in NSG (NOD / SCID / IL2Rgamma- knockout) Beta- 2 microglobulin (B2M) knockout mice engrafted with OVCAR3 ovarian cancer cells. Based on internal data, OVCAR3 is a moderate CLDN6 expressing cell line with approximately 96, 000 copies of CLDN6 per cell. Dosing began once tumors grew to 150 mm3 and there was sufficient engraftment of Human peripheral blood mononuclear cells (" PBMC "). In this xenograft model, almost 100 % efficacy was obtained with twice weekly dosing of 0. 1 or 1 mg / kg CTIM- 76. Based on allometric scaling of the cynomolgus monkey pharmacokinetics to human, a similar level of clinical exposure to the 0. 1 mg / kg dose in the mouse model (i. e., maintaining a Cmin ≥ ~ 100 ng / mL) should be achievable with once weekly dosing of 400 µg to 11, 000 µg CTIM- 76. In preclinical toxicology studies, cynomolgus monkeys received CTIM- 76 once weekly, which supports once weekly dosing in the clinic. Study design: NSG- b2m knockout mice (n = 14 / arm) engrafted with human PBMCs and bearing advanced subcutaneous OVCAR3 tumor xenografts were treated twice per week with vehicle or CTIM- 76. Comparison of CLDN6 development programs We have performed head- to- head in vitro studies comparing internally developed CLDN6 monoclonal and bispecific antibodies and those from Amgen, BioNTech, TORL, and Xencor. Clones of antibodies for Amgen, BioNTech and TORL CLDN6 products were developed internally for benchmarking purposes. Comparative data for Xencor was derived from publicly available reports published independent of us. Comparisons and results may differ in material ways from the actual antibody that is in development. The results presented in the below table have been derived from internal studies and publicly available reports of preclinical studies run independently of our preclinical results. We have not performed any head- to- head clinical trials comparing any of these other therapies with CTIM- 76. As such, the results of these other product candidates may not be comparable to clinical results for CTIM- 76. The design of these other studies vary in material ways from the design of the preclinical studies for CTIM- 76. For further information and to understand these material differences, you should read the relevant publicly available reports. We believe it is useful to compare the in vitro results achieved by Amgen, BioNTech, TORL, and Xencor' s product candidates and approaches as a proxy to understand the estimated selectivity differences of these therapies. Context AmgenTORLXencor BioNTech Program CTIM- 76AMG794TORL- 1- 23XmAb541BNT211Antibody Format Bispecific CLDN6xCD3HLE BiTECLDN6xCD3MMAE ADC2 x 1 Bispecific CLDN6xCD3CLDN6 CAR- TStage PreclinicalPhase 1Phase 1INDPhase 1Status ActiveActiveActiveActiveActiveSelectivity CLDN6: 9 > 1000x > 1000x > 1000x10x7xTolerabilityWell ToleratedPoorModerateWell ToleratedWell Tolerated~~ Our collaboration and license agreements Collaboration Agreement with Tyligand Bioscience In March 2020, we entered into a process development agreement (the " Tyligand Process Development Agreement ") with Tyligand Bioscience (Shanghai) Limited (" Tyligand ") for the development, manufacturing, registration and future commercialization of ONA- XR. **Upon completion of specific performance- based milestones** ~~Under~~ **under** ~~the terms of~~ the Tyligand Process Development Agreement, **in August 2021** ~~Tyligand was solely responsible for the design and optimization of an improved manufacturing process for ONA- XR. Upon completion of specific performance- based milestones~~ , we and Tyligand entered into a license agreement (the " Tyligand License Agreement ") whereby Tyligand was granted the exclusive right to ONA- XR and ~~is~~ **was** solely responsible for the development and commercialization of ONA- XR in China, Hong Kong and Macau ~~(the " Territory ")~~ . We retained rights in the rest of the world to commercialize ONA- XR. ~~The~~ **In August 2024, we and Tyligand mutually agreed to terminate the** Tyligand License Agreement ~~provides for termination in the event of (a) insolvency~~ , ~~(b) a material breach of the agreement,~~ and ~~(c) in the event that~~ **any ongoing payment obligations we may have had to** Tyligand ~~does not meet certain regulatory milestones. For example, we have the ability to terminate the Tyligand License Agreement if Tyligand fails to file and receive acceptance of an investigational new drug for an ONA- XR related product in the People' s Republic of China by August 23, 2024. Under~~ **under** the Tyligand Process Development Agreement ~~, we paid Tyligand $ 0. 8 million and issued 111, 576 warrants to purchase shares of common stock at an exercise price of $ 7. 17 per share upon successful completion of the manufacturing development plan in 2021. The warrants were cancelled in connection with our initial public offering. In addition, $ 2. 0 million would be payable upon the completion of scale- up of the first cumulative 100 kilograms of the Good Manufacturing Practices (" GMP ")- grade compound and $ 3. 0 million upon our completion of scale- up of the first cumulative 300 kilograms of the GMP- grade compound. In consideration of and upon Tyligand' s successful completion of the development plan, within 30 days at the end of each calendar quarter, we shall pay Tyligand 1 % of net sales of finished product utilizing the compound substantially manufactured in accordance with the process and specifications outlined in the Tyligand Process Development Agreement. This agreement terminated in August 2021, subject to certain surviving and ongoing obligations, including the scale up payments and the 1 % net sales payment obligations. Per the Tyligand License Agreement, Tyligand shall pay us a non- refundable, non- creditable royalty at a rate in the mid- single digits of the net sales of each product in the Territory in each calendar quarter commencing with the first commercial sale of such product in the field in the Territory and ending upon the latest of (i) the sale of a generic product in the Territory and (ii) 15 years after the date of the first commercial sale of product in the Territory~~ . Collaboration and Licensing Agreement with Integral Molecular In April 2021, we entered into a collaboration and licensing agreement with Integral Molecular, Inc. (" Integral ") (the " Integral License Agreement ") for the development of a CLDN6 ~~BsAb~~ **bsAb** for cancer therapy. Under the terms of the Integral License Agreement, we and Integral ~~will develop~~ **developed a** CLDN6 **bsAb** ~~bispecific antibodies~~ that **is intended to** trigger the activation of T cells and ~~eliminate~~ **eliminates** cancer cells

displaying CLDN6. We will conduct preclinical and all clinical development, as well as regulatory and commercial activities through exclusive worldwide rights to develop and commercialize the novel CLDN6 candidates ~~. We paid an upfront license fee of $ 0. 3 million and granted 418, 559 shares of Series A Stock with a fair market value of approximately $ 2. 8 million~~ . As a part of the Integral License Agreement, Integral was eligible to receive remaining development and regulatory milestone payments totaling approximately $ 55 million ~~(of which a $ 0. 5 development milestone was achieved in the second quarter of 2022 and subsequently paid)~~ , sales milestone payments totaling up to $ 130 ~~. 0~~ million, and tiered royalties of up to 12 % of net sales of certain products developed under the Integral License Agreement. **On March 20** ~~We were also required to pay royalties on a country- by- country and licensed- by- licensed product basis~~ , **2023** ~~until the later of: (i) the expiration of the patent covering such product in such territory~~ , **we amended** ~~(ii)~~ the ~~expiration of any regulatory exclusivity granted with respect to a product in such territory and (iii) 10 years from the first commercial sale of such product in such country. The~~ Integral License Agreement ~~shall continue in full force and effect, until either~~ (~~a~~ **the " First Amendment "**) ~~royalty payments for all products in all territories have expired or (b) (i) we provide written notice of termination, (ii) during three successive quarters we do not use commercially reasonable efforts to develop a product, (iii) if the agreement is breached or (iv) if a party goes bankrupt. On March 20, 2023, we amended the Integral License Agreement~~ to remove the previously agreed to second milestone payment and to change the amount of the third milestone payment to increase such payment by the amount of the prior second milestone payment and to add payment for third- party research funding obtained and used by Integral in connection with the development of CTIM- 76. On February 29, 2024, we **further** amended the Integral License Agreement to reflect updated financial terms. In the course of our further due diligence review of CTIM- 76, we determined that certain of the licensed rights under the Integral License Agreement may incorporate intellectual property rights currently held by a third party. Specifically, we are aware of issued patents in the United States and certain foreign jurisdictions expiring in January 2034 that potentially cover certain of the intellectual property included in CTIM- 76. While we believe we will have reasonable defenses against any potential claim of infringement, we may not be successful in such efforts, and we also may not be able to obtain a license to such patent on commercially reasonable terms, or at all. As part of Amendment 2 to the Integral License Agreement (**the** " Second Amendment"), Integral ~~'~~ **'** s right to receive certain future payments **was** ~~will be~~ reduced as follows: aggregate development and regulatory milestone payments **were** ~~will be~~ reduced from $ 55 million to $ 15 million, aggregate sales milestone payments **were** ~~will be~~ reduced from $ 130 million to $ 12. 5 million, and a tiered royalty of 8- 12 % that commenced at first commercial sale **was** ~~will be~~ reduced to a flat royalty rate of 6 % on net sales beginning no sooner than February 1, 2034. The Second Amendment also ~~narrows~~ **narrowed** the license grant from Integral to us to only cover CTIM- 76, ~~removes~~ **removed** any further obligation of us to reimburse Integral for any independently obtained research funding Integral applied against CTIM- 76 research, and ~~includes~~ **included** mutual releases by the parties. The reduced development and regulatory milestones now reflect a payment due at each of: first patient' s first screening visit in a Phase 1b / 2 or Phase 2 clinical trial for CTIM- 76, first patient' s first screening visit in a Phase 3 clinical trial for CTIM- 76, United States marketing approval for CTIM- 76, European Union marketing approval for CTIM- 76, United Kingdom marketing approval for CTIM- 76, and Japan marketing approval for CTIM- 76. The amended commercial milestones now also reflect a payment due upon the achievement of annual net sales of $ 500 million and annual net sales of $ 1 billion. **Asset Purchase Agreement with Link On July 9, 2024, we entered into the Asset Purchase Agreement pursuant to which we acquired CT- 95 (formerly known as LNK- 101), from Link, which succeeded to the assets of Link Immunotherapeutics Inc. The FDA previously cleared the IND application for CT- 95. Pursuant to the Asset Purchase Agreement, we purchased all of the Transferred Assets on an " as is " and " where is " basis. CT- 95 patents are currently being prosecuted and / or maintained in the United States, Europe, Canada, Australia, Japan and Taiwan. We also assumed certain liabilities relating to the Transferred Assets. In consideration of the purchase of the Transferred Assets, we made a one- time payment to Link of $ 3. 75 million. Collaboration and Licensing Agreement with BioAtla On September 23, 2024, we entered into the BioAtla License Agreement with BioAtla, pursuant to which we obtained an exclusive, worldwide license to develop, manufacture and commercialize the BioAtla Assets, including BA3362 (renamed by the Company as CT- 202), BioAtla' s Nectin- 4 x CD3 TCE.** Menarini Clinical Trial Collaboration and Supply Agreement On August 1, 2022, we entered into a Clinical Trial Collaboration and Supply Agreement (the " Menarini Agreement ") with Berlin- Chemie AG- Menarini Group- (" Menarini ") **related** ~~. Pursuant~~ to ~~the Menarini Agreement, Menarini agreed to provide, at no cost to us, elacestrant, its nonsteroidal combined selective estrogen receptor modulator and selective estrogen receptor degrader therapy, for use in combination with~~ ONA- XR ~~, in a planned Phase 1 / 2 clinical trial (the " Menarini Study "). Under the Menarini Agreement, we agreed to sponsor, fund and conduct the Menarini Study. Under the Menarini Agreement, Menarini agreed to manufacture and supply elacestrant at Menarini' s cost and for no charge to us for use in the Menarini Study and to provide cell- free nucleic acid analysis of the anonymized blood samples of all Menarini Study patients. We own any data and sample testing results produced in the Menarini Study. We and Menarini jointly own any rights to inventions relating to the combined use of elacestrant and ONA- XR, while Menarini owns certain inventions solely related to elacestrant and we own certain inventions solely related to ONA- XR. We and Menarini formed a joint development committee responsible for coordinating all activities between the parties under the Menarini Agreement. Additionally, had we received a bona- fide third- party offer to sell, divest or license ONA- XR, we would have been required, subject to certain exceptions, to inform Menarini of the receipt of an offer and, if Menarini timely provided proposed terms for such a transaction in writing, we would have been required to consider such terms in good faith~~ . On March 21, 2023, we mutually terminated the Menarini Agreement, and the parties agreed to reasonably cooperate towards an orderly wind- down of the related clinical trial. Commercialization We retain full worldwide development and commercialization rights to certain CLDN6 ~~antibody~~ patents in the field of bispecific antibodies ~~and retain~~ **, full** worldwide development and commercialization rights ~~for ONA~~ **to CT** ~~- XR outside of Greater China~~ **95 patents, and full worldwide development and commercialization rights to certain CT- 202 patents** . We periodically evaluate out- license opportunities for our product

candidates ~~, including our current exploration of strategic options for ONA- XR,~~ and seek to identify drug candidates for novel indications and / or patient subpopulations with an oncology focus that we might in- license. Our commercial plans and strategy for any of our programs may change as programs advance, markets change, and we receive more clinical data, and will depend on availability of current and future capital. Sales and marketing We currently have no sales, marketing, or commercial product distribution capabilities, and we may explore partnerships with larger pharmaceutical organizations that already have these capabilities. We intend to build the necessary infrastructure and capabilities over time for the United States, and potentially other regions, following further advancement of a product candidate. We do not own or operate, and currently have no plans to establish, any manufacturing facilities. We rely, and expect to continue to rely, on third parties for the manufacture of our current and any future product candidates for preclinical and clinical testing, as well as for commercial manufacture if any product candidate obtains marketing approval. We also rely, and expect to continue to rely, on third parties to package, label, store and distribute our current and any future investigational product candidates, as well as for our commercial products if marketing approval is obtained. We believe that this strategy allows us to maintain a more efficient infrastructure by eliminating the need for us to invest in our own manufacturing facilities, equipment and personnel while also enabling us to focus our expertise and resources on the development of our current and any future product candidates. To date, we have obtained active pharmaceutical ingredients (" API ") and drug product for our product candidates from several third- party contract manufacturers **, including Lonza Sales AG (" Lonza Sales ") and Lonza AG (collectively, " Lonza ") and Just- Evotec Biologics, Inc** . We continue to develop our supply chain for CTIM- 76 **, CT- 95 and CT- 202,** and intend to put in place additional framework agreements under which third- party contract manufacturers will generally provide us with necessary quantities of API and drug product on a project- by- project basis based on our development needs. On November 7, 2022, we entered into a ~~Development and Manufacturing Services Agreement (the " Lonza Development Agreement "), with Lonza Sales AG (" Lonza Sales ") and Lonza AG (collectively, " Lonza "). Under the terms of the Lonza Development Agreement, Lonza will provide services relating to the development and manufacture of CTIM- 76 (the " Product ") in accordance with the project plan attached to the Lonza Development Agreement and any other work as may be agreed to between us and Lonza. The Lonza Development Agreement will terminate upon the completion of the agreed upon services, unless earlier terminated by us or Lonza for uncured material breaches, insolvency of the other party, or if a party determines that it is not possible to complete the services for material scientific or material technical reasons. We can terminate certain services under the Lonza Development Agreement, but in addition to payment for certain non- cancellable commitments, we would be required to pay a cancellation fee, such fee to be determined depending on the timing of such notice prior to the commencement of the related services. The License Development Agreement requires us to obtain a license from Lonza prior to receipt from Lonza of the Product or in vivo clinical studies or any other commercial use or sale of the Product, which we entered into concurrently with the License Development Agreement, as further described below. Additionally, should we desire to either manufacture the Product itself or have it manufactured by a third party, we would be required to obtain Lonza' s consent (not to be unreasonably withheld, conditioned or delayed) and would need to enter into a separate technology transfer agreement with Lonza for a non- exclusive license to the extent necessary to manufacture, have manufactured and supply the Product at a licensing fee up to £ 750, 000. The Lonza Development Agreement also contains customary representations, warranties, indemnification and other obligations of us and Lonza. On November 7, 2022, we entered into a~~ License Agreement (the " Lonza **CTIM- 76** License Agreement ") with Lonza Sales. Under the terms of the Lonza **CTIM- 76** License Agreement, to the extent incorporated into ~~the Product~~ **CTIM- 76** , Lonza granted us a non- exclusive license to use certain proprietary Lonza intellectual property and systems for us to develop, manufacture and commercially exploit ~~the Product~~ **CTIM- 76** . We shall pay certain royalties and annual payments in respect of the manufacturing and sale of ~~Product~~ **CTIM- 76** , which amounts shall be determined by the party manufacturing ~~the Product~~ **CTIM- 76** and ranges from a potential annual payment of up to less than $ 500, 000 and a royalty on net sales from 0 % up to a low single digit percentage. The royalty payments and annual payments would be reduced in certain circumstances, including should the valid claims for any such patent rights not exist in the country in which ~~such Product~~ **CTIM- 76** is being sold, and the royalty payments would expire upon the later of the expiration of the licensed patents in the country in which ~~such Product~~ **CTIM- 76** is being sold, the expiration of the licensed patents in the country in which ~~such Product~~ **CTIM- 76** is being manufactured, and 10 years from the first commercial sales of ~~the Product~~ **CTIM- 76** in such country of sale. The Lonza **CTIM- 76** License Agreement continues until terminated, and we or Lonza may terminate the Lonza **CTIM- 76** License Agreement for uncured material breaches or insolvency of the other party. We can unilaterally terminate the Lonza **CTIM- 76** License Agreement with prior written notice to Lonza, and Lonza can also unilaterally terminate the Lonza **CTIM- 76** License Agreement upon certain actions by us. The Lonza **CTIM- 76** License Agreement also contains customary representations, warranties, indemnification and other obligations of us and Lonza. As we advance our current and any future product candidates through development, we will consider our lack of redundant supply for the API and drug product for each product candidate to protect against any potential supply disruptions. We generally expect to rely on third parties for the manufacture of any companion diagnostics we may develop. Competition The pharmaceutical and biotechnology industries are characterized by rapidly advancing technologies, intense competition, and a strong emphasis on proprietary products. While we believe that our technology, the experience of our executive and scientific team, research, clinical capabilities, development experience and scientific knowledge provide us with competitive advantages, we face increasing competition from many different sources, including pharmaceutical and biotechnology companies, academic institutions, governmental agencies and public and private research institutions. Product candidates that we successfully develop and commercialize may compete with existing therapies and new therapies that may become available in the future. Many of our competitors, either alone or with their collaborators, have significantly greater financial resources, established presence in the market, expertise in research and development, manufacturing, preclinical and clinical testing, obtaining regulatory approvals and reimbursement and marketing approved products than we do. These competitors also compete with us in recruiting and retaining qualified scientific and management

personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Smaller or early- stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. Additional mergers and acquisitions may result in even more resources being concentrated in our competitors. Our commercial potential 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 products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market or make our development more complicated. The key competitive factors affecting the success of all of our programs are likely to be efficacy, safety and convenience. For CTIM- 76, our ~~CLDN6xCD3 bispecific antibody~~ **CLDN6 x CD3 TCE** , we are aware of several companies developing ~~antibodies~~ **T cell engagers** against ~~this target~~ **CLDN6. Several TCE candidates are currently in clinical development** , including **those of** ~~Abbvie Inc., Amgen, Astellas Pharma Inc., AstraZeneca plc, BioNTech,~~ Chugai Pharmaceutical ~~Co.~~ **(SAIL66)** , ~~Ltd.~~ **Beigene (BGB- B455)** , **NovaRock Biotherapeutics (NBL028), Third Arc Bio (ARC101), and Xencor (XmAb541). We may face further competition from companies pursuing the development of product candidates that target CLDN6 through other modalities, including** Daiichi Sankyo ~~Company, Limited~~ (**DS9606** ~~" Daiichi Sankyo "~~), ~~I- Mab~~ **BioNTech (BNT211** , **BNT142)** ~~NovaRock Biotherapeutics Inc.~~ , **and** TORL ~~, and Xencor~~ **(TORL- 1- 23)** . ~~These~~ **For CT- 95, our MSLN x CD3 TCE, we are aware of several** companies **developing T cell engagers against MSLN. Several TCE candidates** are **currently** ~~developing CDLN6 products in naked antibody, antibody drug conjugate, bispecific, CAR- T, and mRNA vaccine formats. Multiple products are~~ in clinical development, including those **of Johnson & Johnson (JNJ- 7903421), Zymeworks (ZW171), and Amgen (AMG- 305). We may face further competition** from ~~Amgen~~ **companies pursuing the development of product candidates that target MSLN through other modalities** , **including Pfizer (HBM- 9033), RemeGen Biosciences (RC88), Outpace Bio (OPB- 101), and Navrogen (NAV001, NAV008). For CT- 202, our Nectin- 4 x CD3 TCE, we are aware of several companies developing T cell engagers against Nectin- 4. Several TCE candidates are currently in clinical development, including those of Bicycle Therapeutics (BT7480). We may face further competition from companies pursuing the development of product candidates that target Nectin- 4 through other modalities, including Pifzer (Padcev ®), Bicycle Therapeutics (BT8009), Eli Lilly (LY4052031, LY4101174), Corbus Pharmaceuticals (CRB- 701), Bio- Thera (BAT8007), Mabwell (PMW2821), Adcentrx (ADRX- 0706), Rondo Therapeutics (RNDO- 564), Aktis Oncology (AKY- 1189), and Shanghai Henlius** ~~BioNTech~~ **Biotech (HLX- 309)** ~~, Daiichi Sankyo, and TORL~~ . 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 our patent rights. We retain full worldwide development and commercialization rights to certain CLDN6 antibody patents in the field of bispecific antibodies **, full worldwide development** and ~~we own the issued~~ **commercialization rights to CT- 95** ~~patent~~ **patents ,** and **full worldwide development and commercialization rights to certain CT- 202** ~~patent~~ **patents** ~~applications relating to ONA- XR~~ . Our policy is to seek 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 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 to protect our product candidates and continuing to innovate to develop, strengthen and maintain our proprietary position in the field of oncology. We also plan to rely on data exclusivity, market exclusivity and patent term extensions when available. Our commercial success will depend in part on our ability to obtain and maintain patent and other proprietary protection for our product candidates, technology, inventions and improvements; to preserve the confidentiality of our trade secrets; to defend and enforce our proprietary rights, including any patents that we may own or license in the future; and to operate without infringing on the valid and enforceable patents and other proprietary rights of third parties. As of March 1, ~~2024~~ **2025** , the Integral **Molecular, Inc.** patent portfolio ~~for~~ **covering** CTIM- 76 **and methods of use** that we exclusively licensed pursuant to the Integral License Agreement ~~included~~ **includes** ~~one~~ **two** granted U. S. ~~patent~~ **patents** , ~~two~~ **three** pending U. S. non- provisional applications, one pending International Patent Cooperation Treaty (" PCT ") application, **granted patents in China** ~~four pending U. S. provisional applications~~ , **Eurasia, Japan, Saudi Arabia, Vietnam,** and ~~31~~ **South Africa, and** pending foreign applications **in United Arab Emirates, Australia, Brazil, Canada, Chile, Europe, Hong Kong, Indonesia, Israel, India, South Korea, Mexico, New Zealand, Philippines, Singapore, Thailand, Taiwan and Ukraine. The U. S. patents are expected to expire in 2040 and 2043, subject to any extensions or disclaimers. We own two pending U. S. provisional applications covering CTIM- 76 and methods of using it, which, if converted and issued, will expire in 2045, subject to any extensions or disclaimers. As of March 1, 2025, we own the patent portfolio covering CT- 95 and methods of use, which includes one U. S. patent, one pending U. S. non- provisional application, a pending U. S. provisional application, and pending foreign applications in Australia, Canada, Europe, Japan, and Taiwan** . The U. S. patent is expected to expire in ~~2040~~ **2042** , subject to any extensions or disclaimers. As of March 1, ~~2024~~ **2025** , ~~our~~ **the BioAtla** patent portfolio ~~with respect~~ **covering CT- 202 and methods of use that we exclusively licensed pursuant to the BioAtla License Agreement includes** ~~to~~ **two pending** ~~our ONA- XR product candidate consisted of four issued~~ U. S. **non- provisional** ~~patents, three published PCT~~ applications, ~~four~~ **a** granted **patent in Japan, and pending** foreign **applications in** ~~patents (including one granted Australian~~ - **Australia** ~~patent~~ , ~~one granted Canadian~~ -- **Canada** ~~patent~~ , **China** ~~one granted Chinese patent~~ , **Europe,** ~~and one granted~~ Hong Kong **, Israel, India, Japan, South Korea, Macau, Mexico, Singapore, Thailand, and Taiwan. The issued** patent ~~), eight~~ **and any patents that grant from the** pending ~~foreign patent~~ applications ~~(including two Chinese applications, two Hong Kong applications, two Japanese applications, one Korean application, and one European regional patent application), and one pending U. S. application. Our granted U. S. patents, referenced above, have claims directed to our ONA- XR product candidate as pharmaceutical compositions, formulations, related methods of use, and methods~~

~~of making. These U. S. patents~~ are expected to expire ~~between~~ **from** ~~2035~~ **2039** ~~and 2037~~ **to 2041** , subject to any extensions or disclaimers. We also possess substantial know- how and trade secrets relating to the development and commercialization of our product candidates, including related manufacturing processes and technology. With respect to our current and any future product candidates and processes, we intend to develop and commercialize in the normal course of business, and we intend to pursue patent protection covering, when possible, compositions, methods of use, dosing and formulations. We may also pursue patent protection with respect to manufacturing and drug development processes and technologies. Issued patents can provide protection for varying periods of time, depending upon the date of filing of the patent application, the date of patent issuance and the legal term of patents in the countries in which they are obtained. In general, patents issued for applications filed in the United States can provide exclusionary rights for 20 years from the earliest effective filing date. In addition, in certain instances, the term of an issued U. S. patent that covers or claims an FDA approved product can be extended to recapture a portion of the term effectively lost as a result of the FDA regulatory review period, which is called patent term extension. The restoration period cannot be longer than five years and the total patent term, including the restoration period, must not exceed 14 years following FDA approval. The term of patents outside of the United States varies in accordance with the laws of the foreign jurisdiction, but typically is also 20 years from the earliest effective filing date. However, the actual protection afforded by a patent varies on a product- by- product basis, from country- to- country and depends upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory- related extensions, the availability of legal remedies in a particular country and the validity and enforceability of the patent. The patent positions of companies like ours are generally uncertain and involve complex legal and factual questions. No consistent policy regarding the scope of claims allowable in patents in the field of oncology has emerged in the United States. The relevant patent laws and their interpretation outside of the United States is also uncertain. Changes in either the patent laws or their interpretation in the United States and other countries may diminish our ability to protect our technology or product candidates and could affect the value of such intellectual property. In particular, our ability to stop third parties from making, using, selling, offering to sell or importing products that infringe our intellectual property will depend in part on our success in obtaining and enforcing patent claims that cover our product candidates, technology, inventions and improvements. We cannot guarantee that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications we may file in the future, nor can we be sure that any patents that may be granted to us in the future will be commercially useful in protecting our products, the methods of use or manufacture of those products. Moreover, even our issued patents may not guarantee us the right to commercialize our product candidates, if approved. Patent and other intellectual property rights in the pharmaceutical and biotechnology space are evolving and involve many risks and uncertainties. ~~For example, third~~ **Third** parties may have blocking patents that could be used to prevent us from commercializing our product candidates and practicing our proprietary product candidates, and our issued patents may be challenged, invalidated or circumvented, which could limit our ability to stop competitors from marketing related products or could limit the term of patent protection that otherwise may exist for our product candidates. Moreover, such third parties may obtain damages against us, which could require us to make commercially reasonable royalty payments, payments for lost profits, or other damages, costs and expenses. In addition, the scope of the rights granted under any issued patents may not provide us with protection or competitive advantages against competitors with similar products. Furthermore, our competitors may independently develop similar products that are outside the scope of the rights granted under any issued patents. For these reasons, we may face competition with respect to our product candidates. Moreover, because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before any particular product candidate can be commercialized, any patent protection for such product may expire or remain in force for only a short period following commercialization, thereby reducing the commercial advantage the patent provides. Regulatory Pathway We expect that CTIM- 76 **, CT- 95 and CT- 202** will **each** be classified and regulated by the FDA as a biologic. We expect that any small molecule product that we may develop will be classified and regulated by the FDA as a drug. A new drug application (" NDA ") is required to introduce a drug into interstate commerce. A biologics license application (" BLA ") is required to introduce a biologic product into interstate commerce. The specific requirements of NDAs and BLAs include applicant information, product information, manufacturing information, pre- clinical data, clinical data, and labelling. The most important, time- consuming, and expensive aspect of preparing for a BLA or NDA is conducting clinical trials to demonstrate safety and effectiveness. The requirements of such clinical trials heavily influence the eventual allowable product label claims. The FDA has a performance goal as defined in the Prescription Drug User Fee Act of 10 months for a standard submission and six months for priority review. It is not uncommon for NDAs and BLAs to require medical advisory board review prior to the FDA granting marketing approval. A facility inspection verifying the manufacturing systems is also usually performed prior to FDA approval. We have in the past used and intend to continue to utilize the services of third- party experts to supplement internal regulatory planning and implementation. Ongoing FDA Regulation After the FDA permits a product to enter commercial distribution, numerous and pervasive regulatory requirements continue to apply to our business operations, products and technologies. These include: • the FDA' s quality system regulation ~~, or~~ **(“** QSR **”)** , which requires manufacturers, including third- party manufacturers, to follow stringent design, testing, production, control, supplier / contractor selection, complaint handling, documentation and other quality assurance procedures during all aspects of the manufacturing process; • labeling and marketing regulations which require that promotion is truthful, not misleading, fairly balanced and provide adequate directions for use and that all claims are substantiated; • advertising and promotion requirements, including FDA prohibitions against the promotion of products for uncleared, unapproved or off- label uses and FDA guidance on off- label dissemination of information and responding to unsolicited requests for information; • restrictions on sale, distribution or use; • product establishment, registration and listing requirements and reporting requirements; • recall requirements, including a mandatory recall if there is a reasonable probability that a product would cause serious adverse health consequences or death; • an order of repair, replacement or refund; and • post- market surveillance activities and regulations, which apply when necessary to protect

the public health or to provide additional safety and effectiveness data. The FDA has broad post- market and regulatory enforcement powers. Manufacturers of biologic products and drug products are subject to unannounced inspections by the FDA and other state, local and foreign regulatory authorities to assess compliance with the QSR and other applicable regulations, and these inspections may include the manufacturing facilities of any suppliers. Failure to comply with applicable regulatory requirements can result in enforcement action by the FDA, which may include any of the following sanctions: • warning letters, untitled letters, Form 483s, fines, injunctions, consent decrees and civil penalties; • recall or seizure of products; • operating restrictions, partial suspension or total shutdown of production; • the FDA' s refusal of requests for approval of new products or indications for existing products; • the FDA' s refusal to issue certificates to foreign governments needed to export products for sale in other countries; • withdrawing approvals that have already been granted; and • criminal prosecution. Privacy and Security Laws There are numerous U. S. federal and state laws and regulations related to the privacy and security of personal information, including health information. Among others, the federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act (HITECH), and their implementing regulations, (collectively referred to as " HIPAA "), establish privacy and security standards that limit the use and disclosure of protected health information (" PHI ") and require covered entities and business associates to implement administrative, physical, and technical safeguards to ensure the confidentiality, integrity and availability of individually identifiable health information in electronic form, among other requirements. Violations of HIPAA may result in civil and criminal penalties. Companies subject to HIPAA must also comply with HIPAA' s breach notification rule which requires notification of affected patients and the U. S. Department of Health and Human Services (" HHS "), and in certain cases of media outlets, in the case of a breach of unsecured PHI. The regulations also require business associates of covered entities to notify the covered entity of breaches by the business associate. State attorneys general also have the right to prosecute HIPAA violations committed against residents of their states, and HIPAA standards have been used as the basis for the duty of care in state civil suits, such as those for negligence or recklessness in misusing personal information. In addition, HIPAA mandates that HHS conduct periodic compliance audits of HIPAA covered entities and their business associates for compliance. Many states have laws that protect the privacy and security of sensitive and personal information, including health information, to which we are subject. These laws may be similar to or even more protective than HIPAA and other federal privacy laws. For example, California enacted the California Consumer Privacy Act (the " CCPA "), which creates individual privacy rights for California consumers and increases the privacy and security obligations of entities handling certain personal data. The CCPA went into effect on January 1, 2020, and the California Attorney General may bring enforcement actions for violations as of July 1, 2020. On January 1, 2023, California adopted the California Privacy Rights Act (" CPRA "), which amended the CCPA to enhance certain of the privacy protections for California consumers that were created by the CCPA. The enhancements include imposing additional compliance obligations for covered entities and removing certain exemptions previously available under the CCPA. While the California Attorney General retains civil enforcement authority, the CPRA also created the California Privacy Protection Agency to implement and enforce the law **. Since the CCPA, many other states have passed or are considering passing similar state privacy laws** . We may be subject to other state and federal privacy laws, including laws that prohibit unfair privacy and security practices and deceptive statements about privacy and security, laws that place specific requirements on certain types of activities, such as data security and texting, and laws requiring holders of personal information to maintain safeguards and to take certain actions in response to a data breach. European Union member states, the United Kingdom, Switzerland and other jurisdictions have also adopted data protection laws and regulations, which impose significant compliance obligations. The EU- wide General Data Protection Regulation (" GDPR ") became applicable on May 25, 2018, replacing the previous data protection laws issued by each EU Member State based on the Directive 95 / 46 / EC. Unlike the Directive (which needed to be transposed at national level), the GDPR text is directly applicable in each EU member state, resulting in a more uniform application of data privacy laws across the EU. The GDPR imposes onerous accountability obligations, requiring data controllers and processors to maintain a record of their data processing and policies. It requires data controllers to be transparent and disclose to data subjects (in a concise, intelligible and easily accessible form) how their personal information is to be used, imposes limitations on retention of information, increases requirements pertaining to pseudonymized (i. e., key- coded) data, introduces mandatory data breach notification requirements and sets higher standards for data controllers to demonstrate that they have obtained valid consent for certain data processing activities. Fines for non- compliance with the GDPR are significant — the greater of EUR 20 million or 4 % of global turnover. The GDPR provides that EU Member States may introduce further conditions, including limitations, to the processing of genetic, biometric or health data. In the UK, the UK General Data Protection Regulation (the " UK GDPR ") came into effect on January 1, 2021. Similar to the GDPR, the UK GDPR sets out the key principles, rights, and obligations for most processing of personal data in the UK. The Data Protection Act of 2018, which came into effect on May 25, 2018 and was amended on January 1, 2021, works alongside and supplements the UK GDPR. U. S. Healthcare Reform Changes in healthcare policy could increase our costs and subject us to additional regulatory requirements that may interrupt commercialization of our products. By way of example, the Patient Protection and Affordable Care Act (" PPACA ") substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacted the pharmaceutical, medical device and biologics industries, among others. Since its enactment, there have been judicial and Congressional challenges to certain aspects of PPACA, and there may be additional ~~challenges and~~ amendments to PPACA in the future. For example, in 2017, Congress enacted the Tax Cuts and Jobs Act, which eliminated the tax- based shared responsibility payment imposed by PPACA 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 August 16, 2022, the Inflation Reduction Act of 2022 (the " IRA "), was passed, which among other things, allows for the Centers for Medicare & Medicaid Services (" CMS ") to negotiate prices for certain single- source drugs and biologics reimbursed under Medicare Part B and Part D, beginning with 10 high- cost drugs paid for by Medicare Part D starting in 2026, followed by 15 Part D drugs in 2027, 15 Part B or Part D

drugs in 2028, and 20 Part B or Part D drugs in 2029 and beyond. The legislation subjects drug manufacturers to civil monetary penalties and a potential excise tax for failing to comply with the legislation by offering a price that is not equal to or less than the negotiated " maximum fair price " under the law or for taking price increases that exceed inflation. The legislation also caps Medicare beneficiaries' annual out- of- pocket drug expenses at $ 2, 000. The effect of the IRA on our business ~~and the healthcare industry in general~~ is not yet known. There will continue to be proposals by legislators at both the federal and state levels, regulators and third- party payors to reduce costs while expanding individual healthcare benefits. Certain of these changes could impose additional limitations on the prices we will be able to charge and / or patients' willingness to pay for our products. While in general it is too early to predict what effect, if any, any future healthcare reform legislation or policies will have on our business, current and future healthcare reform legislation and policies could have a material adverse effect on our business and prospects. Pricing and Reimbursement In the United States and markets in other countries, sales of any products for which we receive regulatory approval for commercial sale will depend in part on the availability of reimbursement from third- party payors. Third- party payors include government health administrative authorities, managed care providers, private health insurers, and other organizations. These third- party payors are increasingly challenging the price and examining the cost- effectiveness of medical products and services. In addition, significant uncertainty exists as to the reimbursement status of newly approved healthcare products, and efforts are underway to reduce the cost of medical products and services overall. We may need to conduct expensive studies in order to demonstrate the cost- effectiveness of our products. Our current and any future product candidates may not be considered cost- effective. Decisions regarding the extent of coverage and amount of reimbursement to be provided are made on a plan- by- plan basis. One third- party payor' s decision to cover a particular product or procedure using the product does not ensure that other payors will also provide coverage for the product. Adequate third- party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate revenue level. Future legislation could limit payments for our current and any future product candidates. The U. S. government, state legislatures and foreign governments have shown significant interest in implementing cost containment programs to limit the growth of government- paid health care costs, including price controls, restrictions on reimbursement and requirements for substitution of less costly products. Adoption of government controls and measures, and tightening of restrictive policies in jurisdictions with existing controls and measures, could limit payments for our products. The marketability of any products for which we receive regulatory approval for commercial sale may suffer if the government and third- party payors fail to provide adequate coverage and reimbursement. In addition, an increasing emphasis on managed care in the United States has increased and will continue to increase the pressure on medical product and service pricing. Anti- Kickback and False Claims Laws In the United States, the research, manufacturing, distribution, sale and promotion of pharmaceutical products and devices are subject to regulation by various federal, state and local authorities in addition to the FDA, including CMS, other divisions of HHS (e. g., the Office of Inspector General), the U. S. Department of Justice, state Attorneys General, and other federal, state and local government agencies. For example, sales, marketing and scientific / educational grant programs must comply with the Federal Food, Drug, and Cosmetic Act, the Anti- Kickback Statute, as amended, the False Claims Act, as amended, the privacy regulations promulgated under HIPAA, and similar state laws. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. All of these activities are also potentially subject to federal and state consumer protection and unfair competition laws. As noted above, in the United States, we are subject to complex laws and regulations pertaining to healthcare " fraud and abuse, " including, but not limited to, the federal Anti- Kickback Statute, the federal False Claims Act, and other state and federal laws and regulations. The Anti-Kickback Statute makes it illegal for any person, including a biological product manufacturer (or a party acting on its behalf) to knowingly and willfully solicit, receive, offer, or pay any remuneration that is intended to induce the referral of business, including the purchase or order of an item for which payment may be made under a federal healthcare program, such as Medicare or Medicaid. Violations of this law are punishable by up to five years in prison, criminal fines, administrative civil money penalties, and exclusion from participation in federal healthcare programs. In addition, many states have adopted laws similar to the Anti- Kickback Statute. Some of these state prohibitions apply to the referral of patients for healthcare services reimbursed by any insurer, not just federal healthcare programs such as Medicare and Medicaid. Due to the breadth of these federal and state anti- kickback laws and the potential for additional legal or regulatory change in this area, it is possible that our sales and marketing practices and / or our relationships with physicians might be challenged under anti- kickback laws, which could harm us. Because we plan to commercialize products that could be reimbursed under a federal healthcare program and other governmental healthcare programs, we plan to develop a comprehensive compliance program that establishes internal controls to facilitate adherence to the rules and program requirements to which we are subject. The federal False Claims Act prohibits anyone from, among other things, knowingly presenting, or causing to be presented, for payment to federal programs (including Medicare and Medicaid) claims for items or services, including pharmaceutical products, that are false or fraudulent. Although we would not submit claims directly to payers, manufacturers can be held liable under these laws if they are deemed to " cause " the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers or promoting a product off- label. In addition, our activities relating to the reporting of wholesaler or estimated retail prices for our products, the reporting of prices used to calculate Medicaid rebate information and other information affecting federal, state, and third- party reimbursement for our products, and the sale and marketing of our products, are subject to scrutiny under this law. For example, pharmaceutical companies have been prosecuted under the federal False Claims Act in connection with their off- label promotion of drugs. Penalties for a False Claims Act violation include three times the actual damages sustained by the government, plus mandatory civil penalties for each separate false claim, the potential for exclusion from participation in federal healthcare programs, and, although the federal False Claims Act is a civil statute, conduct that results in a False Claims Act violation may also implicate various federal criminal statutes. If the government were to allege that we were, or convict us of, violating these false claims laws, we could be subject to a substantial fine and may suffer a decline in

our stock price. In addition, private individuals have the ability to bring actions under the federal False Claims Act and certain states have enacted laws modeled after the federal False Claims Act. There are also an increasing number of state laws that require manufacturers to make reports to states on pricing and marketing information. Many of these laws contain ambiguities as to what is required to comply with the laws. In addition, a provision of PPACA, referred to as the Sunshine Act, requires pharmaceutical product manufacturers to track and report to the federal government certain payments or other transfers of value made to physicians, registered nurses and teaching hospitals, among others, in the previous calendar year. These laws may affect our sales, marketing, and other promotional activities by imposing administrative and compliance burdens on us. In addition, given the lack of clarity with respect to these laws and their implementation, our reporting actions could be subject to the penalty provisions of the pertinent state and federal authorities. Other Federal Healthcare Fraud and Abuse Laws We may also be subject to other federal healthcare fraud and abuse laws, including provisions of HIPAA, which prohibit knowingly and recklessly executing a scheme or artifice to defraud any healthcare benefit program, including private payors, as well as knowingly and willfully falsifying, concealing or covering up a material fact by any trick, scheme or device or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. A violation of this statute is a felony and may result in fines, imprisonment or exclusion from government- sponsored programs. Similar to the federal Anti- Kickback Statute, a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation. Foreign Corrupt Practices Act The Foreign Corrupt Practices Act (the " FCPA "), prohibits U. S. businesses and their representatives from offering to pay, paying, promising to pay or authorizing the payment of money or anything of value to a foreign official in order to influence any act or decision of the foreign official in his or her official capacity or to secure any other improper advantage in order to obtain or retain business. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring us to maintain books and records, which in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the corporation, including international subsidiaries, if any, and to devise and maintain a system of internal accounting controls sufficient to provide reasonable assurances regarding the reliability of financial reporting and the preparation of financial statements. The scope of the FCPA includes interactions with certain healthcare professionals in many countries. Human Capital As of March 1, ~~2024~~ **2025** , we had ~~five~~ **twelve** full- time employees and no part- time employees. None of these employees are represented by labor unions or covered by collective bargaining agreements. We believe that our employee relations are good. Culture is a critical element in the management of our organization. Our talented employees are focused on driving our business with the foundation for all our efforts being to advance medicines for solid tumors. Our goal is that each colleague feels a deep connection to what they do, loves coming to work, and is aligned to our mission. Culture begins with our hiring process and continues throughout an employee' s time with Context. We support our colleagues with a comprehensive offering of competitive pay and benefits. Facilities Our principal office is located in Philadelphia, Pennsylvania, where we lease approximately 3, 500 square feet of office space pursuant to a lease that expires on November 30, ~~2024~~ **2026** , which lease ~~automatically~~ renews **at our option** for **two additional** successive ~~three~~ **one** - ~~month~~ **year** periods ~~unless~~ **should** we ~~or~~ **provide** the landlord ~~provides the other~~ with ~~a termination~~ notice **of extension** at least ~~90 days~~ **9 months** before any such successive renewal. We believe our facility is adequate to meet our current needs, although we may seek to negotiate new leases or evaluate additional or alternate space for our operations. We believe appropriate alternative space will be readily available on commercially reasonable terms. Legal Proceedings From time to time we may be involved in disputes or litigation relating to claims arising out of our operations. We are not currently a party to any legal proceedings that could reasonably be expected to have a material adverse effect on our business, financial condition and results of operations. Corporate Information We were incorporated under the laws of the State of Delaware in April 2021. Our corporate office is located at 2001 Market Street, Suite 3915, Unit # 15, Philadelphia, PA 19103. Our telephone number is (267) 225- 7416. We maintain an Internet website at www. contexttherapeutics. com. The information contained on our website is not incorporated by reference into this Form 10- K. We make available free of charge under the " Investors & News " — " Financials " — " SEC Filings " section of our website all of our filings with the SEC, including our annual reports on Form 10- K, quarterly reports on Form 10- Q, current reports on Form 8- K, proxy statements and amendments to such documents, each of which is provided on our website as soon as reasonably practicable after we electronically file or furnish, as applicable, the information with the SEC. Item 1A. Risk Factors Investing in our common stock involves a high degree of risk. You should consider carefully the risks and uncertainties described below, together with general economic and business risks and all of the other information contained in this Annual Report on Form 10- K, including the section titled " Management' s Discussion and Analysis of Financial Condition and Results of Operations " and our financial statements and related notes, before making a decision to invest in our common stock. Our business, results of operations, financial condition or prospects could also be harmed by risks and uncertainties that are not presently known to us or that we currently believe are not material. If any of the risks actually occur, our business, results of operations, financial condition and prospects could be materially and adversely affected. In that event, the market price of our common stock could decline, and you could lose all or part of your investment. This Annual Report on Form 10- K also contains forward- looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward- looking statements as a result of specific factors, including the risks described below. See" Note Regarding Forward- Looking Statements." We have not commercialized any products and have yet to generate any revenue from product sales. The amount of our future net losses will depend, in part, on our expenses and our ability to generate revenues. Our current and any future product candidates will require substantial additional development time and resources before we may realize revenue from product sales, if at all. We expect to continue to incur significant expenses and operating losses for the foreseeable future. We anticipate that our expenses will increase substantially if and as we: • continue our current research and development programs, including conducting laboratory, preclinical and clinical studies for product candidates; • **continue and** initiate clinical trials for product candidates; • seek to identify, assess, acquire or develop additional research programs or product candidates; • maintain,

expand and protect our intellectual property portfolio; • seek marketing approvals for any product candidates that may successfully complete development; • establish a sales, marketing and distribution infrastructure to commercialize any products that may obtain marketing approval; • further develop and refine the manufacturing process for our current and any future product candidates; • change or add additional manufacturers or suppliers of pharmaceutical or biological materials or product candidates; • acquire or in- license other technologies; • seek to attract and retain new and existing personnel; and • expand our facilities. ~~No~~ **We recently began our clinical trial for CTIM- 76 and no** clinical studies have begun on ~~CTIM~~ **CT** - ~~76~~ **95 or CT- 202** . It will be several years, if ever, before we obtain regulatory approval for a therapeutic product candidate, at which time any revenues for such product candidate will depend upon many factors, including market conditions, costs and effectiveness of manufacturing, sales, marketing and distribution operations related to such product candidate, the scope of intellectual property protection for such product candidate, and the terms of any collaboration or other strategic arrangement we may have with respect to such product candidate and levels of reimbursement from third- party payors. If we are unable to develop and commercialize one or more product candidates either alone or with collaborators, including through the potential out- licensing of our product candidates, or if revenues from any product candidate that receives marketing approval or is commercialized are insufficient, we may not achieve profitability or sustain profitability, which would have an adverse effect on the value of our common stock, which would be materially adversely affected. The continuation of our business is dependent upon raising additional capital. We will need additional funding to meet our operational needs and capital requirements for clinical trials, other research and development expenditures, and general and administrative expenses. We currently have no credit facility or committed sources of capital. ~~We believe our cash and cash equivalents of $ 14. 4 million as of December 31, 2023 are not sufficient to fund our projected operations for a period of at least the 12 months from the issuance date of the accompanying consolidated financial statements. As a result, we have concluded that there is substantial doubt about our ability to continue as a going concern within one year after the date that the accompanying consolidated financial statements are issued. The accompanying consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America, which contemplate continuation of the Company as a going concern and the realization of assets and satisfaction of liabilities in the normal course of business. Moreover, the carrying amounts of assets and liabilities presented in the accompanying consolidated financial statements (i) do not necessarily purport to represent realizable or settlement values and (ii) do not include any adjustment that might result from the outcome of this uncertainty or any adjustments relating to the recoverability of assets and classification of assets and liabilities that might be necessary should we be unable to continue as a going concern.~~ Until such time, if ever, as we can generate substantial product revenue, we expect to finance our operations through a combination of equity offerings, debt financings, collaborations, strategic transactions and / or marketing, distribution or licensing arrangements. There can be no assurances that our plans to obtain additional capital will be successful on the terms or timeline we expect, or at all. If these efforts are unsuccessful, we may be required to significantly curtail or discontinue operations or, if available, to obtain funds through financing transactions with unfavorable terms. The process of identifying product candidates and conducting preclinical and clinical trials is time consuming, expensive, uncertain and takes years to complete. Our operations have consumed substantial amounts of cash since inception. We expect our expenses to increase in connection with our ongoing activities, particularly as we identify, continue the research and development of, initiate clinical trials of, and seek marketing approval for, product candidates. Our future funding requirements, both near and long- term, will depend on many factors, including, but not limited to: • initiation, progress, timing, costs and results of preclinical studies and clinical trials, including patient enrollment in such trials, for CTIM- 76 **, CT- 95, CT- 202** or any other future product candidates; • clinical development plans we **have established and may** establish for CTIM- 76 **, CT- 95, CT- 202** and any other future product candidates; • obligation to make milestone, royalty and non- royalty sublicense receipt payments to third- party licensors, if any, under our licensing agreements; • number and characteristics of product candidates that we discover or in- license and develop; • outcome, timing and cost of regulatory review by the FDA and comparable foreign regulatory authorities, including the potential for the FDA or comparable foreign regulatory authorities to require that we perform more studies than those that we currently expect; • costs of filing, prosecuting, defending and enforcing any patent claims and maintaining and enforcing other intellectual property rights; • effects of competing technological and market developments; • costs and timing of the implementation of commercial- scale manufacturing activities; and • costs and timing of establishing sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval. Adequate additional financing may not be available to us on acceptable terms, or at all. If we are unable to obtain sufficient funding on a timely basis or on favorable terms, we may be required to significantly delay, reduce or eliminate one or more of our research or product development programs and / or commercialization efforts or we might have to obtain funds through arrangements, such as out- licensing our product candidates, with collaborative partners or others that may require us to relinquish rights to our technologies or product candidates that we otherwise would not relinquish. We may also be unable to expand our operations or otherwise capitalize on business opportunities as desired. Any of these events could materially adversely affect our financial condition and business prospects **. If we are not able to successfully integrate recent and future acquisitions, our management' s attention could be diverted, and efforts to integrate future acquisitions could consume significant resources. Our recent obtainment of the rights to CT- 202 and the acquisition of CT- 95, and any other future acquisition that we may undertake, involve risks related to the integration of the acquired assets into the Company after the acquisition is completed. These risks include delays in development timelines, increased expenses, and assumption of undisclosed liabilities** . We are a biopharmaceutical company with a limited operating history. We were founded in 2015 and spent the first three years of our company' s history developing and refining our therapeutic approach, and only since then have we focused our efforts on advancing the development of product candidates. Investment in biopharmaceutical product development is a highly speculative endeavor and entails substantial upfront capital expenditures. There is significant risk that any product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, obtain any required regulatory

approvals or become commercially viable. Our product candidates and the therapeutic approach we are using are new and unproven. We had commenced Phase 2 human clinical trials for ONA- XR, but we ceased development of this product candidate and have **only recently initiated clinical trials for one of our other product candidates, and we have** not demonstrated an ability to ~~initiate clinical trials for our other product candidate or~~ successfully complete any clinical trials, obtain any required marketing approvals, manufacture products, conduct sales, marketing and distribution activities, or arrange for a third party to do any of the foregoing on our behalf. Consequently, any predictions made about our future success or viability may not be as accurate as they could be if we had a history of successfully developing and commercializing products. Our limited operating history, particularly in light of the rapidly evolving nature of the biopharmaceutical industries and the cancer therapeutics field, may make it difficult to evaluate our technology and business prospects or to predict our future performance. Research programs to identify new product candidates require substantial technical, financial, and human resources. We may focus our efforts and resources on potential programs or product candidates that ultimately prove to be unsuccessful. The successful completion of a clinical trial with regard to any of our product candidates is not assured despite the expenditure of significant resources in pursuit of their development, and our spending on current and future research and development programs and product candidates may not yield any commercially viable products. Additionally, if we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other strategic arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate. **We have vendors located outside of** ~~In November 2022, we entered into~~ the **United States that** ~~Lonza Development Agreement, pursuant to which Lonza has provided~~ **provide** services relating to the development and manufacture of ~~CTIM- 76. As~~ **our product candidates, and as** a result, we have had and expect to continue to have more significant foreign currency risks related to our operating expenses denominated in currencies other than the U. S. dollar. A weakening U. S. dollar could increase our operating expenses, which would adversely impact our results of operations and financial position **. While inflation in the United States has been relatively low in recent years, the economy in the United States has encountered a material level of inflation since 2021. Although inflation eased somewhat in 2024, it has raised our costs for commodities, labor, materials, and services and other costs required to grow and operate our business, and failure to secure these on reasonable terms may adversely impact our financial condition. Additionally, increases in inflation, along with public health concerns, geopolitical developments, and global supply chain disruptions, have caused, and may in the future cause, global economic uncertainty and uncertainty about the interest rate environment, which may make it more difficult, costly, or dilutive for us to secure additional financing. A failure to adequately respond to these risks could have a material adverse impact on our financial condition, results of operations, or cash flows** . Our governing documents designate the Court of Chancery of the State of Delaware as the sole and exclusive forum for certain types of state law actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, employees or agents. Our amended and restated certificate of incorporation provides that, unless we consent in writing to the selection of an alternative form, the Court of Chancery of the State of Delaware (or, if the Court of Chancery does not have jurisdiction, the United States District Court for the District of Delaware) will be the sole and exclusive forum for: (1) any derivative action or proceeding brought on our behalf; (2) any action asserting a claim of breach of a fiduciary duty or other wrongdoing by any of our directors, officers, employees or agents to us or our stockholders; (3) any action asserting a claim against us arising pursuant to any provision of the General Corporation Law of the State of Delaware or our amended and restated certificate of incorporation or amended and restated bylaws; (4) any action to interpret, apply, enforce or determine the validity of our amended and restated certificate of incorporation or amended and restated bylaws; or (5) any action asserting a claim governed by the internal affairs doctrine. In addition, our amended and restated certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States of America shall, to the fullest extent permitted by law, be the sole and exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act of 1933, as amended (the " Securities Act "). Notwithstanding the foregoing, the exclusive forum provision shall not apply to claims seeking to enforce any liability or duty created by the Securities Exchange Act of 1934, as amended (the " Exchange Act "). This choice of forum provision may limit our stockholders' ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, employees or agents, which may discourage such lawsuits against us and our directors, officers, employees and agents even though an action, if successful, might benefit our stockholders. Stockholders who do bring a claim in the Court of Chancery could face additional litigation costs in pursuing any such claim, particularly if they do not reside in or near Delaware. The Court of Chancery may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments or results may be more favorable to us than to our stockholders. Alternatively, if a court were to find this provision inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could have a material adverse effect on our business, financial condition or results of operations. Risks Related to our Product Candidates We have no products approved for sale. The success of our business, including our ability to finance our ~~company~~ **Company** and generate any revenue in the future, will primarily depend on the successful development, regulatory approval and commercialization of CTIM- 76 **, CT- 95 and CT-202** , which may never occur. In the future, we may also become dependent on other product candidates that we may develop or acquire; however, not all of our product candidates have been tested in humans and given our early stage of development, it may be many years, if at all, before we have demonstrated the safety and efficacy of a cancer treatment sufficient to warrant approval for commercialization. We have not previously submitted ~~a~~ **an** NDA or BLA to the FDA, or similar regulatory approval filings to comparable foreign authorities, for any product candidate, and we cannot be certain that our current or any future product

candidates will be successful in clinical trials or receive regulatory approval. Further, any future product candidates may not receive regulatory approval even if they are successful in clinical trials. If we do not receive regulatory approvals for our current or future product candidates, we may not be able to continue our operations. Even if we successfully obtain regulatory approvals to market a product candidate, our revenue will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval and have commercial rights. If the markets or patient subsets that we are targeting are not as significant as we estimate, we may not generate significant revenues from sales of such products, if approved. We plan to seek regulatory approval to commercialize our current and any future product candidates both in the United States and in selected foreign countries. While the scope of regulatory approval generally is similar in other countries, in order to obtain separate regulatory approval in other countries **,** we must comply with numerous and varying regulatory requirements of such countries regarding safety and efficacy. Other countries also have their own regulations governing, among other things, clinical trials and commercial sales, as well as pricing and distribution of our current and any future product candidates, and we may be required to expend significant resources to obtain regulatory approval and to comply with ongoing regulations in these jurisdictions. The clinical and commercial success of our current and any future product candidates will depend on a number of factors, including the following: • our ability to raise ~~any~~ additional required capital on acceptable terms, or at all; • our ability to complete IND and BLA- enabling studies and successfully submit an IND and BLA; • timely completion of our preclinical studies and clinical trials, which may be slower or cost more than we currently anticipate and will depend substantially upon the performance of third- party contractors; • whether we are required by the FDA or similar foreign regulatory agencies to conduct additional clinical trials or other studies beyond those planned to support approval of our product candidates; • **the results of our clinical trials; •** acceptance of our proposed indications and primary endpoint assessments relating to the proposed indications of our product candidates by the FDA and similar foreign regulatory authorities; • our ability to consistently provide for manufacturing of our product candidates **or future approved products, if any,** on a timely basis; • our ability, and the ability of any third parties with whom we contract, to remain in good standing with regulatory agencies and **to** develop, validate and maintain commercially viable manufacturing processes that are compliant with current good manufacturing practices (" cGMPs "); • our ability to demonstrate to the satisfaction of the FDA and similar foreign regulatory authorities the safety, efficacy and acceptable risk- benefit profile of our product candidates; • the prevalence, duration and severity of potential side effects or other safety issues experienced with our product candidates or future approved products, if any; • the timely receipt of necessary marketing approvals from the FDA and similar foreign regulatory authorities; • achieving and maintaining, and, where applicable, ensuring that our third- party contractors achieve and maintain, compliance with our contractual obligations and with all regulatory requirements applicable to our ~~lead~~ product ~~candidate~~ **candidates** or any future product candidates or **future** approved products, if any; • the willingness of physicians, operators of hospitals and clinics and patients to utilize or adopt our product ~~candidate~~ **candidates** or any future product candidates; • our ability to successfully develop a commercial strategy and thereafter commercialize our current or any future product candidates in the United States and internationally, if approved for marketing, sale and distribution in such countries and territories, whether alone or in collaboration with others, including through the potential out- licensing of **our product candidates; • competition from other applicants' products authorized for marketing before or after we receive regulatory authorization, if any, for** our product candidates; • the availability of coverage and adequate reimbursement from managed care plans, private insurers, government payors (such as Medicare and Medicaid) and other third- party payors for any of our product candidates that may be approved; • the convenience of our treatment or dosing regimen; • acceptance by physicians, payors and patients of the benefits, safety and efficacy of our current or any future product candidates, if approved, including relative to alternative and competing treatments; • patient demand for our current or future product candidates, if approved; • our ability to establish and enforce intellectual property rights in and to our product candidates; and • our ability to avoid third- party patent interference, intellectual property challenges or intellectual property infringement claims. These factors, many of which are beyond our control, could cause us to experience significant delays or an inability to obtain regulatory approvals or commercialize our current or future product candidates. Even if regulatory approvals are obtained, we may never be able to successfully commercialize any product candidates. Accordingly, we cannot provide assurances that we will be able to generate sufficient revenue through the sale of our product ~~candidate~~ **candidates** or any future product candidates to continue our business or achieve profitability. Our innovative therapy approach is based on novel ideas and technologies that are unproven and may not result in marketable products, which exposes us to unforeseen risks and makes it difficult for us to predict the time and cost of product development and potential for regulatory approval. Our foundational science and product development approach are based on the selective targeting of solid- tumor cancers ~~, including by inhibiting CLDN6~~ to elicit meaningful anticancer activity. We believe that this approach may offer an improved therapeutic effect by redirecting T- cell- mediated lysis toward malignant cells expressing **the tumor antigens that are targeted (** CLDN6 **, MSLN or Nectin- 4)** . However, this approach to treating cancer is novel and the scientific research that forms the basis of our efforts to develop therapeutics that effectively inhibit membrane protein targets is both preliminary and limited. As such, we cannot assure you that even if we are able to develop cancer therapeutic candidates capable of redirecting T- cell- mediated lysis toward malignant cells, that such therapy would safely and effectively treat cancers. We may spend substantial funds attempting to develop this approach and never succeed in developing a marketable therapeutic. Furthermore, no regulatory authority has granted approval for a **T cell redirecting** cancer therapy based on a selective targeting of ~~Claudin 6~~ **CLDN6, MSLN or Nectin- 4** positive cancers. As such, we believe the FDA has limited experience with evaluating our approach, which may increase the complexity, uncertainty and length of the regulatory approval process for our product ~~candidate~~ **candidates** . We may never receive approval to market and commercialize any product candidate. Even if we obtain regulatory approval, the approval may be for targets, disease indications, lines of therapy or patient populations that are not as broad as we intended or desired or may require labeling that includes significant use or distribution restrictions or safety warnings. The results of preclinical studies, early clinical trials or analyses of a product candidate may not be predictive of the

results of later- stage clinical trials. A product candidate in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. In addition, conclusions based on promising data from analyses of clinical results may be shown to be incorrect when implemented in prospective clinical trials. Even if our future clinical trials are completed as planned, we cannot be certain that their results will support the safety and efficacy sufficient to obtain regulatory approval. From time to time, we may publish interim " top- line " or preliminary data from our clinical studies. Interim or preliminary data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Preliminary or " top-line " data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim and preliminary data should be viewed with caution until the final data are available. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects. Serious adverse events or undesirable side effects caused by a product candidate could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign authorities. Results of any clinical trial we conduct could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. For example, certain patients treated with ONA- XR, our former product candidate, experienced adverse events that included, but were not limited to, fatigue, liver enzyme elevations and nausea. If unacceptable side effects arise in the development of any product candidate, we, the FDA or the institutional review boards (" IRBs ") at the institutions in which our studies are conducted, or the data safety monitoring board, if constituted for our clinical trials, could recommend a suspension or termination of our clinical trials, or the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of a product candidate for any or all targeted indications. In addition, drug- related side effects could affect patient recruitment or the ability of enrolled patients to complete a trial or result in potential product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff. We expect to have to train medical personnel using a product candidate to understand the side effect profiles for our clinical trials and upon any commercialization of any product candidate. Inadequate training in recognizing or managing the potential side effects of any product candidate could result in patient injury or death. Any of these occurrences may harm our business, financial condition and prospects significantly. Additionally, if any product candidate receives marketing approval, and we or others later identify undesirable side effects caused by such product, a number of potentially significant negative consequences could result, including: • regulatory authorities may withdraw approvals of such product; • regulatory authorities may require additional warnings on the label, such as a " black box " warning or contraindication; • additional restrictions may be imposed on the marketing of the particular product or the manufacturing processes for the product or any component thereof; • we may be required to implement a Risk Evaluation and Mitigation Strategy (" REMS "), or create a medication guide outlining the risks of such side effects for distribution to patients; • we could be sued and held liable for harm caused to patients; • the product may become less competitive; and • our reputation may suffer. Any of these events could prevent us from achieving or maintaining market acceptance of a product candidate, if approved, and could significantly harm our business, results of operations and prospects. ~~Our~~ **Successful and timely completion of clinical trials will require that we identify and enroll a specified number of patients for each of our clinical trials. We may not be able to initiate or continue clinical trials for our** current **or any future product candidates if we are unable to identify and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside the United States. Subject enrollment, a significant factor in the timing of clinical trials, is affected by many factors, including the size and characteristics of the patient population, the proximity of patients to clinical sites, the eligibility and exclusion criteria for the trial, the design of the clinical trial, the ability to obtain and maintain informed consents, the risk that enrolled patients will not complete a clinical trial, our ability to recruit clinical trial investigators with the appropriate competencies and experience, and competing clinical trials and clinicians' and patients' perceptions as to the potential advantages and risks of the** product candidate ~~and~~ **being studied in relation to other available therapies, including any new products that may be approved for the indications we are investigating as well as any** product **candidates under** development ~~program~~ **. We will be required to identify and enroll a sufficient number of patients for each of our clinical trials and monitor such patients adequately during and after treatment. Potential patients for any planned clinical trials may not be adequately diagnosed or identified with the diseases that we are targeting, which could adversely impact the outcomes of our trials and could have safety concerns for the potential patients. Potential patients for any planned clinical trials may also not meet the entry criteria for such trials. Additionally, other pharmaceutical companies targeting these same diseases are recruiting clinical trial patients from these patient populations, which may make it more difficult to fully enroll our clinical trials. The process of finding and recruiting patients may prove costly. The timing of our clinical trials depends, in part, on the speed at which we can recruit patients to participate in our trials, as well as completion of required follow- up periods. The eligibility criteria of our clinical trials, once established, may further limit the pool of available trial participants. If patients are unwilling or unable to participate in our trials for any reason, including the existence of concurrent clinical trials for similar target populations, the availability of approved or authorized therapies, or the fact that enrolling in our trials may prevent patients from taking a different product, or we otherwise have difficulty enrolling a sufficient number of patients, the timeline for recruiting patients, conducting trials, and obtaining regulatory approval of our product candidates may be delayed. Our inability to enroll a specified number of patients for any of our future clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether. We cannot assure you that our assumptions used in determining expected clinical trial timelines are correct or that we will not experience delays or**

difficulties in enrollment, or be required by the FDA or other regulatory authorities to increase our enrollment, which would result in the delay of completion of such trials beyond our expected timelines. We recently initiated clinical trials for CTIM- 76, anticipate dosing the first patient in the CT- 95 Phase 1 trial in the second quarter of 2025, and CT- 202 is still in the IND validation process. We may be unsuccessful in advancing any product candidate **during clinical development or otherwise** into clinical development or in identifying and developing additional product candidates. Our ability to identify and develop product candidates is subject to the numerous risks associated with preclinical **, clinical** and early stage biopharmaceutical development activities, including that: • we may not be able to assemble sufficient resources to acquire or discover additional product candidates, including through the potential out- licensing of our product candidates; • we may not be able to enter into collaborative arrangements to facilitate development of product candidates; • competitors may develop alternatives that render our product candidates obsolete or less attractive; • our product candidates may be covered by third parties' patents or other exclusive rights; • the regulatory pathway for a product candidate may be too complex, expensive or otherwise difficult to navigate successfully; or • our product candidates may be shown to not be effective, have harmful side effects or otherwise pose risks not outweighed by such product candidate' s benefits or have other characteristics that may make the products impractical to manufacture, unlikely to receive any required marketing approval, unlikely to generate sufficient market demand or otherwise not achieve profitable commercialization. Even if we do commence additional clinical trials of product candidates and continue to identify new product candidates, such product candidates may never be approved. Failure to successfully identify and develop new product candidates and obtain regulatory approvals for our products would have a material adverse effect on our business and financial condition and could cause us to cease operations. If a product candidate does not achieve projected development milestones or commercialization in the announced or expected timeframes, the further development or commercialization of such product candidate may be delayed, and our business will be harmed. We sometimes estimate, or may in the future estimate, the timing of the accomplishment of various scientific, clinical, manufacturing, regulatory and other product development objectives. These milestones may include our expectations regarding the commencement or completion of scientific studies or clinical trials, the submission of regulatory filings, the receipt of marketing approval or the realization of other commercialization objectives. The achievement of many of these milestones may be outside of our control. All of these milestones are based on a variety of assumptions, including assumptions regarding capital resources, constraints and priorities, progress of and results from development activities and the receipt of key regulatory approvals or actions, any of which may cause the timing of achievement of the milestones to vary considerably from our estimates. **For example, in 2024 we adjusted our guidance regarding the anticipated dosing of the first patient in the CTIM- 76 Phase 1 trial.** If we or our collaborators fail to achieve announced milestones in the expected timeframes, the commercialization of the affected product candidate may be delayed, our credibility may be undermined, our business and results of operations may be harmed, and the price of our common stock may decline. Product liability lawsuits against us could cause us to incur substantial liabilities and could limit commercialization of any products that we develop alone or with collaborators. We face an inherent risk of product liability and professional indemnity exposure related to the testing in clinical trials of our product candidates. We will face an even greater liability risk if we commercially sell any products that we or our collaborators may develop for human use. Manufacturing defects, errors in product distribution or storage processes, improper administration or application and known or unknown side effects of product usage may result in liability claims against us or third parties with which we have relationships. These actions could include claims resulting from acts by our collaborators, licensees and subcontractors over which we have little or no control. For example, our liability could be sought by patients participating in clinical trials for potential therapeutic product candidates as a result of unexpected side effects, improper product administration or the deterioration of a patient' s condition, patient injury or even death. Criminal or civil proceedings might be filed against us by patients, regulatory authorities, biopharmaceutical companies and any other third party using or marketing any product candidates or products that we develop alone or with collaborators. On occasion, large judgments have been awarded in class action lawsuits based on products that had unanticipated adverse effects. If we cannot successfully defend ourselves against claims that product candidates or products we develop alone or with collaborators caused harm, we could incur substantial liabilities. Clinical development does not always fully characterize the safety and efficacy profile of a new medicine, and it is always possible that a drug or biologic, even after regulatory approval, may exhibit unforeseen side effects. If any product candidate were to cause adverse side effects during clinical trials or after approval, we may be exposed to substantial liabilities. Product liability insurance coverage may not be adequate to cover all liabilities that we may incur. We anticipate that we will need to increase our insurance coverage when we expand our clinical trials and if we or our collaborators successfully commercialize any products. As of March 1, ~~2024~~ **2025** , we had ~~five~~ **twelve** full- time employees. We also have various consultants who we rely on for research and development, business development and other services. While we believe this structure enables us to reduce certain infrastructure costs, the small size of our centralized team may limit our ability to devote adequate personnel, time and resources to support the operations of our business, including our research and development activities, and the management of financial, accounting and reporting matters. If our centralized team fails to provide adequate administrative, research and development, or other services across our entire organization, our business, financial condition and results of operations could be harmed. Our future success depends on our ability to retain our Chief Executive Officer, Chief **Medical Officer, Chief** Financial Officer, Chief Legal Officer, and other key executives and to attract, retain and motivate qualified personnel. We are highly dependent on the research and development experience, technical skills, leadership and continued service of certain members of our management and scientific teams, including Martin Lehr, our Chief Executive **Officer, Dr. Claudio Dansky Ullmann, our Chief Medical** Officer, Jennifer Minai- Azary, our Chief Financial Officer, and Alex Levit, our Chief Legal Officer. Although we have formal employment agreements with all of our executive officers, these agreements do not prevent them from terminating their employment with us at any time. The loss of the services of any of these persons could impede the achievement of our research, development and commercialization objectives. ~~The consulting services~~

~~of Tarek Sahmoud, our Chief Medical Officer, ended as of December 31, 2023.~~ Recruiting and retaining qualified scientific, clinical, manufacturing and, if we retain commercialization responsibility for any product candidate we develop alone or with collaborators, sales and marketing personnel, will also be critical to our success. We may not be able to attract and retain these personnel on acceptable terms or at all 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 strategies. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. The inability to recruit, integrate, motivate and retain additional skilled and qualified personnel, or the loss of services of certain executives, key employees, consultants or advisors, may impede the progress of our research, development and commercialization objectives and have a material adverse effect on our business. We will need to expand our organization, and we may experience difficulties in managing this growth, which could disrupt our operations. We will need to significantly expand our organization, and our future financial performance, ability to develop and commercialize product candidates alone or with collaborators and ability to compete effectively will depend in part on our ability to effectively manage any future growth. We may have difficulty identifying, hiring and integrating new personnel. Many of the biopharmaceutical companies that we compete against for qualified personnel and consultants have greater financial and other resources, different risk profiles and a longer history than we do. If we are unable to continue to attract and retain high- quality personnel and consultants, the rate and success at which we can identify and develop product candidates, enter into collaborative arrangements and otherwise operate our business will be limited. Future growth would impose significant additional responsibilities on our management, including the need to identify, recruit, maintain, motivate and integrate additional employees, consultants and contractors. Management may need to divert a disproportionate amount of its attention away from our day- to- day activities and devote a substantial amount of time to managing these growth activities. 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 expected expansion of our operations or recruit and train additional qualified personnel. Moreover, the expected physical expansion of our operations may lead to significant costs and may divert our management and business development resources from other projects, such as the development of product candidates. If we are not able to effectively manage the expansion of our operations, it may result in weaknesses in our infrastructure, increase our expenses more than expected, give rise to operational mistakes, loss of business opportunities, loss of employees, consultants and contractors and reduced productivity. Our insurance policies are expensive and protect us only from some business risks, which leaves us exposed to significant uninsured liabilities. We do not carry insurance for all categories of risk that our business may encounter. If we obtain marketing approval for any product candidates that we or our collaborators may develop, we intend to acquire insurance coverage to include the sale of commercial products, but we may be unable to obtain such insurance on commercially reasonable terms or in adequate amounts. We do not carry specific biological or hazardous waste insurance coverage, and our property, casualty and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and clinical trials or regulatory approvals for any product candidate could be suspended. As a public company it is more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified individuals to serve on our board of directors, our board committees or as our executive officers. In the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses. We do not know if we will be able to maintain existing insurance with adequate levels of coverage, and any liability insurance coverage we acquire in the future may not be sufficient to reimburse us for any expenses or losses we may suffer. A successful liability claim or series of claims brought against us could require us to pay substantial amounts and cause our share price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business, including preventing or limiting the development and commercialization of product candidates. Adverse developments affecting the financial services industry, such as actual events or concerns involving liquidity, defaults, or non- performance by financial institutions ~~or transactional counterparties~~ , could adversely affect our current and projected business operations, financial condition and results of operations. Actual events involving limited liquidity, defaults, non- performance or other adverse developments that affect financial institutions ~~, transactional counterparties~~ or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market- wide liquidity problems. For example, on March 10, 2023, Silicon Valley Bank (" SVB ") was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation (" FDIC ") as receiver. Subsequently, in March 2023, First Citizens BancShares acquired SVB. Inflation and rapid increases in interest rates have led to a decline in the trading value of previously issued government securities with interest rates below current market interest rates. Although the U. S. Department of Treasury, FDIC and Federal Reserve Board announced a program in March 2023 to provide up to $ 25 billion of loans to financial institutions secured by certain of such government securities held by financial institutions to mitigate the risk of potential losses on the sale of such instruments, widespread demands for customer withdrawals or other liquidity needs of financial institutions for immediate liquidity may exceed the capacity of such a program. Additionally, there is no guarantee that the U. S. Department of Treasury, FDIC and Federal Reserve Board will provide access to uninsured funds in the future in the event of the closure of other banks or financial institutions, or that they would do so in a timely fashion. ~~Our access to funding sources in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by factors that affect us, the~~

financial institutions with which we have relationships, or the financial services industry or economy in general. These factors could include, among others, events such as liquidity constraints or failures, the ability to perform obligations under various types of financial, credit or liquidity agreements or arrangements, the loss of uninsured deposits, disruptions or instability in the financial services industry or financial markets, or concerns or negative expectations about the prospects for companies in the financial services industry. In addition, any further deterioration in the macroeconomic economy or financial services industry could lead to losses or defaults by our suppliers or collaboration partners, which in turn, could have a material adverse effect on our current and / or projected business operations and results of operations and financial condition. For example, a collaboration partner may fail to make payments when due, default under their agreements with us, become insolvent or declare bankruptcy, or a supplier may determine that it will no longer deal with us as a customer. In addition, a supplier or collaboration partner could be adversely affected by any of the liquidity or other risks that are described above or by the loss of the ability to draw on existing credit facilities involving a troubled or failed financial institution . Any supplier or collaboration partner bankruptcy or insolvency, or the failure of any collaboration partner to make payments when due, or any breach or default by a supplier or collaboration partner, or the loss of any significant supplier or collaboration partner relationships, could result in material losses to us and may have a material adverse impact on our business. We expect to, and do, depend on collaborations with third parties for certain research, development and commercialization activities, and if any such collaborations are not successful, it may harm our business and prospects. Working with collaborators poses several significant risks, including the following: • limited availability of resource allocation and other developmental decisions made by our collaborators about the product candidates that we seek to develop with them may result in the delay or termination of research programs, studies or trials, repetition of or initiation of new studies or trials or provision of insufficient funding or resources for the completion of studies or trials or the successful marketing and distribution of any product candidates that may receive approval; • collaborators could independently develop, or develop with third parties, product candidates that compete directly or indirectly with our product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours; • collaborators may not properly obtain, maintain, enforce or defend our intellectual property or proprietary rights or may use our proprietary information in such a way that could jeopardize or invalidate our proprietary information or expose us to potential litigation; and • disputes may arise between us and our collaborators that result in the delay or termination of the research, development or commercialization activities or that result in costly litigation or arbitration that diverts management attention and resources. Our ability to generate revenues from these arrangements will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements. If our collaborations, including those in which we may out- license our product candidates, do not result in the successful development and commercialization of product candidates, or if one of our collaborators terminates its agreement with us, we may not receive the expected deliverables or services from our collaborators, nor receive any future funding or milestone or royalty payments under the collaboration. If we do not receive the funding or deliverables or services from our collaborators that we expect under these agreements, our development of product candidates could be delayed and we may need additional resources to develop such product candidates. In addition, if one of our collaborators terminates its agreement with us, we may find it more difficult to find a suitable replacement collaborator or attract new collaborators and may need to raise additional capital to pursue further development or commercialization of the applicable product candidates. These events could delay development programs and negatively impact the perception of our company in business and financial communities. Failure to develop or maintain relationships with any current collaborators could result in the loss of opportunity to work with that collaborator or reputational damage that could impact our relationships with other collaborators in the relatively small industry communities in which we operate. Moreover, all of the risks relating to product development, regulatory approval and commercialization described in this Form 10- K apply to the activities of our collaborators. If our existing collaboration agreements or any collaborative or strategic relationships we may establish in the future are not effective and successful, it may damage our reputation and business prospects, delay or prevent the development and commercialization of product candidates and inhibit or preclude our ability to realize any revenues. We may become involved in disagreements or disputes with our licensees, licensors and other counterparties relating to the development and / or commercialization of our current or past product candidates, which may be time consuming, costly and could harm our efforts to develop our current or future product candidates. We have entered into various agreements and licenses with licensees, licensors and other counterparties related to the development and / or commercialization of our current and past product candidates. These agreements and licenses impose a variety of obligations on us and the counterparties to such agreements and licenses. Disagreements and disputes between us and certain counterparties may arise, such as regarding each parties' obligations under the respective agreement or license. Any such disagreement or dispute could become time consuming, costly and could harm our efforts to develop current or future product candidates. Any disagreements or disputes with such parties that lead to litigation, arbitration or similar proceedings will result in us incurring significant legal expenses and potential significant legal liability and could jeopardize our ability to continue development of the related product candidate. Further, any disagreements or disputes over our obligations or intellectual property that we have licensed or acquired may prevent or impair our ability to maintain our current arrangements on acceptable terms. If we fail to meet our obligations under these agreements or licenses, the respective counterparty may have the right to terminate the respective agreement or license and to re- obtain the related technology as well as aspects of any intellectual property controlled by us and developed during the period the agreement or license was in force that relates to the applicable technology. While we would expect to exercise our rights and remedies available to us in the event we fail to meet our obligations under such agreement or license in any material respect and otherwise seek to preserve our rights under the technology licensed to or acquired by us, we may not be able to do so in a timely manner, at an acceptable cost or at all. Any uncured breach under any agreement or license relating to a product candidate could result in our loss of rights and may lead to a complete termination of the respective agreement or license. Termination of one of these agreements or licenses for any reason

could prevent us from completing a transaction to sell or out- license a product candidate. Additionally, any disagreements or disputes over our counterparties ' obligations or intellectual property rights that we have licensed or acquired may prevent or impair our ability to develop any of our product candidates. If any counterparty fails to meet their obligations under these agreements or licenses or does not have the right to intellectual property rights that they may contractually claim to have, it could materially impact our development of such product candidate. While we may have the right to terminate the respective agreement or license and to maintain some or all of the related technology as well as some or all aspects of any intellectual property controlled by such counterparty, we may not be able to do so in a timely manner, at an acceptable cost or at all, and it may lead to litigation, arbitration or similar proceedings that may result in us incurring significant legal expenses and jeopardize our ability to continue development of the related product candidate. A dispute regarding, or termination of, one of these agreements or licenses for any reason also could prevent us from completing a transaction to sell or out- license a product candidate for which we have decided to discontinue development. We have relied on and we expect to continue to rely on third parties to conduct, supervise and monitor our clinical trials and some aspects of our research and preclinical testing, and if those third parties do not successfully carry out their contractual duties, comply with regulatory requirements, or otherwise perform in a satisfactory manner, we may not be able to obtain regulatory approval or commercialize product candidates, or such approval or commercialization may be delayed, and our business may be substantially harmed. We have relied on and we expect to continue to rely on medical institutions, clinical investigators, contract laboratories and other third parties, such as contract research organizations (" CROs "), to conduct preclinical studies and clinical trials for product candidates. Nevertheless, we are responsible for ensuring that each of our studies and trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on such third parties will not relieve us of our regulatory responsibilities. For example, we remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with regulations, commonly referred to as good clinical practices (" GCPs "), for conducting, monitoring, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. Although we have designed and intend to design future trials for product candidates either alone or with collaborators, third parties may conduct some parts of or all of the trials. As a result, many important aspects of our research and development programs, including their conduct and timing, will be outside of our direct control. Our reliance on third parties to conduct current and future studies and trials will also result in less direct control over the management of data developed through studies and trials than would be the case if we were relying entirely upon our own staff. Communicating with outside parties can also be challenging, potentially leading to mistakes and difficulties in coordinating activities. Such third parties may have staffing difficulties, fail to comply with contractual obligations, experience regulatory compliance issues, undergo changes in priorities, become financially distressed or form relationships with other entities, some of which may be our competitors. We also face the risk of potential unauthorized disclosure or misappropriation of our intellectual property by CROs or other third parties, which may reduce our trade secret protection and allow our potential competitors to access and exploit our proprietary technology. For any violations of laws and regulations during the conduct of our preclinical studies and clinical trials, we could be subject to warning letters or enforcement action that may include civil penalties up to and including criminal prosecution. If we, our collaborators, our CROs or other third parties fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We also are required to register certain ongoing clinical trials and post the results of such completed clinical trials on a government- sponsored database, within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions. If our CROs or other third parties do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for any other reasons, trials for a product candidate may be extended, delayed or terminated, and we or our collaborators may not be able to obtain regulatory approval for, or successfully commercialize, any product candidates. If we are required to repeat, extend the duration of or increase the size of any trials we conduct, it could significantly delay commercialization and require significantly greater expenditures. As a result of any of these factors, our financial results and the commercial prospects for the affected product candidate would be harmed, our costs could increase and our ability to generate revenues could be delayed. If we are unable to obtain sufficient quantities of raw materials and supplies, at acceptable prices and on a timely basis, it could harm our business. We are dependent on third parties for the supply of various pharmaceutical and biological materials and the manufacture of product supplies that are necessary to produce our current and any future product candidates. The supply of these materials 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. Changing 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 or our collaborators may not be able to develop, manufacture and market the affected product candidate in a timely and competitive manner, or at all. If any product candidate receives approval, we will likely need to seek alternative sources of supply of raw materials or manufactured product supplies and there can be no assurance that we will be able to establish such relationships to provide such supplies on commercially reasonable terms or at acceptable quality levels, if at all. If we are unable to identify and procure additional sources of supply that fit our required needs, we could face substantial delays or incur additional costs in procuring such materials. We do, and may further, rely on third parties for the manufacturing process of our current and any future product candidates, and failure by those parties to adequately perform their obligations could harm our business. We do not currently

own any facility that may be used as our clinical- scale manufacturing and processing facility and do rely, and expect that we will continue to rely, on outside vendors, including vendors outside the United States, for at least a portion **, if not all,** of the manufacturing process of our current and any future product candidates that we or our collaborators develop. The facilities used by our contract manufacturers to manufacture product candidates must be approved by the FDA or other foreign regulatory agencies pursuant to inspections conducted after we submit an application to the FDA or other foreign regulatory agencies. When we or our collaborators engage third parties for manufacturing services, we will not control the manufacturing process of, and will be completely dependent on, our contract manufacturing providers for compliance with cGMP requirements for manufacture of the product candidates. We have not yet caused any product candidates to be manufactured or processed on a commercial scale and may not be able to do so. We will make changes as we work to optimize the manufacturing process, and we cannot be sure that even minor changes in the process will result in products that are safe and effective. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or other regulatory authorities, they will not be able to secure and / or maintain regulatory approval for their manufacturing facilities. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market any of our or our collaborators' potential products. If we are not able to establish collaborations on commercially reasonable terms, we may have to alter our research, development and commercialization plans. Our research and product development programs and the potential commercialization of our current and any future product candidates will require substantial additional cash to fund expenses, and we expect that we will continue to seek collaborative arrangements, including the potential out- licensing of **some or all of** our product candidates, for the development and potential commercialization **of some or all** of our current and any future product candidates or the development of ancillary technologies. We face significant competition in establishing relationships with appropriate collaborators. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator' s resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator' s evaluation of a number of factors. Those factors may include, among other things and as applicable for the type of potential product, an assessment of the opportunities and risks of our product ~~candidate~~ **candidates** , the design or results of studies or trials, the likelihood of approval, if necessary, by the U. S. Department of Agriculture, the FDA or similar regulatory authorities outside the United States, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products and industry and market conditions generally. Collaborations are complex and time- consuming to negotiate and document. We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we do enter into additional collaboration agreements, the negotiated terms may force us to relinquish rights that diminish our potential profitability from development and commercialization of the subject product candidate or others. Such collaborations may also impact our ability to control the nature, timing and cadence of developing and commercializing the product candidates subject to such collaborations. If we are unable to enter into additional collaboration agreements, we may have to curtail the research and development of the product candidate for which we are seeking to collaborate, reduce or delay research and development programs, delay potential commercialization timelines, reduce the scope of any sales or marketing activities or undertake research, development or commercialization activities at our own expense. The research, testing, manufacturing, labeling, approval, selling, import, export, marketing, and distribution of drug products, including biologics and pharmaceuticals, are subject to extensive regulation by the FDA and other regulatory authorities in the United States. We expect the novel nature of our product candidates to create further challenges in obtaining regulatory approval. For example, the FDA has limited experience with commercial development of ~~anti- CLDN6N~~ **CLDN6, MSLN and Nectin- 4** therapies for cancer. The FDA may also require a panel of experts, referred to as an Advisory Committee, to deliberate on the adequacy of the safety and efficacy data to support licensure. The opinion of the Advisory Committee, although not binding, may have a significant impact on our ability to obtain licensure of product candidates based on the completed clinical trials, as the FDA often makes decisions consistent with the Advisory Committee' s recommendations. Accordingly, the regulatory approval pathway for our product candidates may be uncertain, complex, expensive and lengthy, and approval may not be obtained. We may also experience delays in completing planned clinical trials for a variety of reasons, including delays related to: • obtaining regulatory authorization to begin a trial, if applicable; • the availability of financial resources to commence and complete the planned trials; • reaching agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites; • obtaining approval at each clinical trial site by an independent IRB; • recruiting suitable patients to participate in a trial; • having patients complete a trial, including having patients enrolled in clinical trials dropping out of the trial before the product candidate is manufactured and returned to the site, or return for post- treatment follow- up; • clinical trial sites deviating from trial protocol or dropping out of a trial; • addressing any patient safety concerns that arise during the course of a trial; • adding new clinical trial sites; or • manufacturing sufficient quantities of qualified materials under cGMPs and applying them on a patient by patient basis for use in clinical trials. We could also encounter delays if physicians encounter unresolved ethical issues associated with enrolling patients in clinical trials of a product candidate in lieu of prescribing existing treatments that have established safety and efficacy profiles. Further, a clinical trial may be suspended or terminated by us, the IRBs for the institutions in which such trials are being conducted or by the FDA or other regulatory authorities due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other

regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product candidate, changes in governmental regulations or administrative actions, lack of adequate funding to continue the clinical trial, or based on a recommendation by the Data Safety Monitoring Committee. The FDA' s review of our data of our clinical trials may, depending on the data, also result in the delay, suspension or termination of one or more clinical trials, which would also delay or prevent the initiation of our other planned clinical trials. If we experience termination of, or delays in the completion of, any clinical trial of a product candidate, the commercial prospects for such product candidate will be harmed, and our ability to generate product revenue will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product development and approval process and jeopardize our ability to commence product sales and generate revenue. Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may ultimately lead to the denial of regulatory approval of our current and any future product candidates. The Biologics Price Competition and Innovation Act was enacted as part of PPACA to establish an abbreviated pathway for the approval of biosimilar and interchangeable biological products. The regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as " interchangeable " based on its similarity to an approved biologic. Under the Biologics Price Competition and Innovation Act, an application for a biosimilar product cannot be approved by the FDA until 12 years after the reference product was approved under a BLA. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty. **Regulatory decisions** ~~The processes intended to implement~~ **implementing** the Biologics Price Competition and Innovation Act may have a material adverse effect on the future commercial prospects for our biological products. We believe that CTIM- 76, **CT- 95 and CT- 202,** if approved in the United States as ~~a~~ biological ~~product~~ **products** under ~~a BLA~~ **BLAs** , should qualify for the 12- year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise ~~, or that the FDA will not consider the subject product candidates to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated~~ . Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of the reference products in a way that is similar to traditional generic substitution for non- biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing. If and when our clinical trials for our current and any future product candidates are completed and, assuming positive data, we expect to advance to potential registrational trials. The general approach for FDA approval of a new biologic or drug is for the sponsor to provide dispositive data from two well- controlled, Phase 3 clinical studies of the relevant biologic or drug in the relevant patient population. Phase 3 clinical studies typically involve hundreds of patients, have significant costs and take years to complete. If the results from our clinical trials are sufficiently compelling, we intend to discuss with the FDA submission of a BLA ~~or NDA, as applicable~~ for the relevant product candidate. However, we do not have any agreement or guidance from the FDA that our regulatory development plans will be sufficient for submission of a BLA ~~or NDA, as applicable~~ for the relevant product candidate. For example, the FDA may require that we conduct a comparative trial against an approved therapy, which would significantly delay our development timelines and require substantially more resources. As well, in 2022 the Oncology Center of Excellence (OCE) of the FDA implemented Project Optimus to reform the dose optimization and dose selection paradigm in oncology drug development, which **has impacted and** could **continue to** impact our **current and** future clinical trials and significantly delay our development timelines and require substantially more resources. The FDA may grant accelerated approval for a product candidate and, as a condition for accelerated approval, the FDA may require a sponsor of a drug or biologic 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 drug or biologic may be subject to withdrawal procedures by the FDA that are more accelerated than those available for regular approvals. We believe an accelerated approval strategy may be warranted given the limited alternatives for patients that our product ~~candidate~~ **candidates** ~~targets~~ **target** , but the FDA may ultimately require a Phase 3 clinical trial prior to approval. In addition, the standard of care may change with **the use of currently approved products or** the approval of new products in the same indications that we are studying. This may result in the FDA or other regulatory agencies requesting additional studies to show that our product ~~candidate~~ **candidates** ~~is~~ **are** superior to the new products. Our clinical trial results may also not support approval. In addition, our current and any future product candidates could fail to receive regulatory approval for many reasons, including the following: • the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials; • we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that our current or any future product candidates are safe and effective for any of their proposed indications; • the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval, including due to the heterogeneity of patient populations; • we may be unable to demonstrate that our current and any future product candidates' clinical and other benefits outweigh their safety risks; • the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials; • the data collected from clinical trials of our current and any future product candidates may not be sufficient to the satisfaction of the FDA or comparable foreign regulatory authorities to support the submission of a BLA ~~or NDA, as applicable,~~ or other comparable submission in foreign jurisdictions or to obtain regulatory approval in the United States or elsewhere; • the FDA or comparable foreign regulatory authorities will review our manufacturing process and inspect our commercial manufacturing facility and may not approve our manufacturing process or facility; and • the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval. Obtaining and maintaining regulatory approval of a product candidate in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing approval of a product candidate, comparable regulatory

authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials as clinical studies conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval. We may also submit marketing applications in other countries. Regulatory authorities in jurisdictions outside of the United States have requirements for approval of product candidates with which we must comply prior to marketing in those jurisdictions. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we fail to comply with the regulatory requirements in international markets and / or receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our current and any future product candidates will be harmed. We will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense, and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with a product candidate. Any regulatory approvals that we receive for a product candidate will require surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require a REMS in order to approve a product candidate, 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. In addition, if the FDA or a comparable foreign regulatory authority approves a product candidate, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for that product candidate will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post- marketing information and reports, registration, as well as continued compliance with cGMPs and GCPs for any clinical trials that we conduct post- approval. As such, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any BLA, other marketing applications and previous responses to inspectional observations. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control. In addition, the FDA could require us to conduct another study to obtain additional safety or biomarker information. Further, we will be required to comply with FDA promotion and advertising rules, which include, among others, standards for direct- to- consumer advertising, restrictions on promoting products for uses or in patient populations that are not described in the product' s approved uses (known as " off- label use "), limitations on industry- sponsored scientific and educational activities and requirements for promotional activities involving the internet and social media. Later discovery of previously unknown problems with a product candidate, including adverse events of unanticipated severity or frequency, or with our third- party suppliers or manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post- market studies or clinical studies to assess new safety risks; or imposition of distribution restrictions or other restrictions under a risk evaluation and mitigation strategy program. Other potential consequences include, among other things: • restrictions on the marketing or manufacturing of a product candidate, withdrawal of the product from the market or voluntary or mandatory product recalls; • fines, warning letters or holds on clinical trials; • refusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or revocation of license approvals; • product seizure or detention, or refusal to permit the import or export of a product candidate; and • injunctions or the imposition of civil or criminal penalties. The FDA' s and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our current and any future product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. 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 and we may not achieve or sustain profitability. The use of T cell engaging bispecific antibodies as potential cancer treatments is a recent development and may not become broadly accepted by physicians, patients, hospitals, cancer treatment centers and others in the medical community and we may not be able to convince them to use a product candidate for many reasons. Additional factors will influence whether a product candidate is accepted in the market, including: • the clinical indications for which a product candidate is approved; • physicians, hospitals, cancer treatment centers and patients considering a product candidate as safe and effective treatments; • the potential and perceived advantages of a product candidate over alternative treatments; • the prevalence and severity of any side effects; • product labeling or product insert requirements of the FDA or other regulatory authorities; • limitations or warnings contained in the labeling approved by the FDA or other regulatory authorities; • the timing of market introduction of a product candidate as well as competitive products; • the cost of treatment in relation to alternative treatments; • the availability of coverage and adequate reimbursement by third- party payors and government authorities; • the willingness of patients to pay out- of- pocket in the absence of coverage and adequate 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. If a product candidate is approved but fails to achieve market acceptance among physicians, patients, hospitals, cancer treatment centers or others in the medical community, we will not be able to generate significant revenue. Even if our products 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. Successful sales of a product candidate, if approved, depend on the availability of coverage and adequate reimbursement from third- party payors, including governmental healthcare

programs, such as Medicare and Medicaid, managed care organizations and commercial payors, among others. Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which we obtain regulatory approval. In addition, because our product candidates represent new approaches to the treatment of cancer, we cannot accurately estimate the potential revenue from our product candidates. Patients who are provided medical treatment for their conditions generally rely on third- party payors to reimburse all or part of the costs associated with their treatment. Obtaining coverage and adequate reimbursement from third- party payors is critical to new product acceptance. Third- party payors decide which drugs and treatments they will cover and the amount of reimbursement. Reimbursement by a third- party payor may depend upon a number of factors, including, but not limited to, the third- party payor' s determination that use of a product is: • a covered benefit under its health plan; • safe, effective and medically necessary; • appropriate for the specific patient; • cost- effective; and • neither experimental nor investigational. Obtaining coverage and reimbursement 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 the payor supporting scientific, clinical and cost- effectiveness data for the use of our products. Even if we obtain coverage for a given product, if the resulting reimbursement rates are insufficient, hospitals may not approve our product for use in their facility or third- party payors may require co- payments that patients find unacceptably high. Patients are unlikely to use a product candidate unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of that product candidate. 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, CMS revises the reimbursement systems used to reimburse health care providers, including the Medicare Physician Fee Schedule and Outpatient Prospective Payment System, which may result in reduced Medicare payments. In some cases, private third- party payers rely on all or portions of Medicare payment systems to determine payment rates. Changes to government healthcare programs that reduce payments under these programs may negatively impact payments from private third- party payers, and reduce the willingness of physicians to use a product candidate. In the United States, no uniform policy of coverage and reimbursement for products exists among third- party payors. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. Further, one payor' s determination to provide coverage for a product does not assure that other payors will also provide coverage for the product. Adequate third- party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development. We intend to seek approval to market our current and any future product candidates in both the United States and in selected foreign jurisdictions. If we obtain approval in one or more foreign jurisdictions for a product candidate, we will be subject to rules and regulations in those jurisdictions. In some foreign countries, particularly those in Europe, the pricing of drugs and biologics is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after obtaining marketing approval of a product candidate. Some of these countries may require the completion of clinical trials that compare the cost- effectiveness of a particular product candidate to currently available therapies. Other member states allow companies to fix their own prices for medicines, but monitor and control company profits. The downward pressure on health care costs 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. The marketability of any product candidates for which we receive regulatory approval for commercial sale may suffer if government and other third- party payors fail to provide coverage and adequate reimbursement. We expect downward pressure on pharmaceutical pricing to continue. Further, coverage policies and third- party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future. The advancement of healthcare reform may negatively impact our ability to sell our current and any future product candidates, if approved, profitably. In the United States and other jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes and proposed changes to the healthcare system that could affect our future results of operations. In particular, there have been and continue to be a number of initiatives at the U. S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare. For example, in March 2010, PPACA was enacted, which substantially changed the way healthcare is financed by both governmental and private payors. Among the provisions of PPACA of importance to the pharmaceutical and biotechnology industries, which includes biologics, are the following: • manufacturers and importers of certain biologics with annual sales of more than $ 5 million made to or covered by specified federal healthcare programs are required to pay an annual, nondeductible fee according to their market share of all such sales; • an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program, to 23. 1 % of the average manufacturer price for most branded drugs, biologics, and biosimilars and to 13. 0 % for generic drugs, and a cap of the total rebate amount for innovator drugs at 100 % of the Average Manufacturer Price; • a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for certain drugs and biologics, including our product candidates, that are inhaled, infused, instilled, implanted, or injected; • extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations; • expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for individuals with income at or below 133 % of the federal poverty level, thereby potentially increasing manufacturers' Medicaid rebate liability; • expansion of the entities eligible for discounts under the Public Health program, commonly referred to as the " 340B Program; " • a ~~new~~ requirement to annually report drug samples that manufacturers and distributors provide to physicians, also known as the " Physician Payments Sunshine Act; " • a ~~new~~ Patient- Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; • establishment of a Center for Medicare Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending; and • a licensure framework for

follow- on biologic products. Since its enactment, there have been judicial and Congressional challenges to certain aspects of PPACA, and there may be additional challenges and amendments to PPACA in the future. For example, in 2017, Congress enacted the Tax Cuts and Jobs Act, which repealed the tax- based shared responsibility payment imposed by PPACA on certain individuals who fail to maintain qualifying health coverage that is commonly referred to as the " individual mandate. " In addition, other legislative changes have been proposed and adopted in the United States since PPACA was enacted which, among other things, have reduced Medicare payments to several types of providers, including hospitals and cancer treatment centers. For example, on August 16, 2022, the IRA, was passed, which among other things, allows for CMS to negotiate prices for certain single- source drugs and biologics reimbursed under Medicare Part B and Part D, beginning with 10 high- cost drugs paid for by Medicare Part D starting in 2026, followed by 15 Part D drugs in 2027, 15 Part B or Part D drugs in 2028, and 20 Part B or Part D drugs in 2029 and beyond. The legislation subjects drug manufacturers to civil monetary penalties and a potential excise tax for failing to comply with the legislation by offering a price that is not equal to or less than the negotiated " maximum fair price " under the law or for taking price increases that exceed inflation. The legislation also caps Medicare beneficiaries' annual out- of- pocket drug expenses at $ 2, 000. The effect of the IRA on our business and the healthcare industry in general is not yet known. These new laws or any other similar laws introduced in the future, as well as regulatory actions that may be taken by CMS, may result in additional reductions in Medicare and other healthcare funding, which could negatively affect our customers and accordingly, our financial operations. Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. Additionally, individual states in the United States have passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing and costs. Similar developments have occurred outside of the United States, including in the European Union where healthcare budgetary constraints have resulted in restrictions on the pricing and reimbursement of medicines by relevant health service providers. To obtain reimbursement or pricing approval in some European Union member states, we may be required to conduct studies that compare the cost- effectiveness of a product candidate to other therapies that are considered the local standard of care. We cannot predict the likelihood, nature, or extent of government regulation that may arise from future legislation or administrative action in the United States 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, a product candidate may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability. The patent positions of biopharmaceutical companies and other actors in our fields of business can be highly uncertain and typically involve complex scientific, legal and factual analyses. In particular, the interpretation and breadth of claims allowed in some patents covering biopharmaceutical compositions may be uncertain and difficult to determine, and are often affected materially by the facts and circumstances that pertain to the patented compositions and the related patent claims. The standards of the United States Patent and Trademark Office (the " USPTO ") and its foreign counterparts are sometimes uncertain and could change in the future. Consequently, the issuance and scope of patents cannot be predicted with certainty. Patents, if issued, may be challenged, invalidated or designed around. U. S. patents and patent applications may also be subject to interference or derivation proceedings, and U. S. patents may be subject to reexamination, post- grant review and / or inter parties review proceedings in the USPTO. International patents may also be subject to opposition or comparable proceedings in the corresponding international patent office, which could result in either loss of the patent or denial of the patent application, or loss or reduction in the scope of one or more of the claims of the patent or patent application. In addition, such interference, derivation, reexamination, post- grant review, inter partes review and opposition proceedings may be costly. Accordingly, rights under any issued patents may not provide us with sufficient protection against competitive products or processes. Furthermore, even if not challenged, our patents and patent applications may not adequately protect our technology and product candidates or products that we develop alone or with collaborators or prevent others from designing their products to avoid being covered by our claims. If the breadth or strength of protection provided by the patents and patent applications that we hold with respect to our product candidates or potential products is threatened, it could dissuade companies from collaborating with us to develop, and could threaten our or their ability to successfully commercialize, such product candidates or potential products. In addition, changes in, or different interpretations of, patent laws in the United States and other countries may permit others to use our discoveries or to develop and commercialize our technology and product candidates or products without providing any compensation to us, or may limit the scope of patent protection that we are able to obtain. The laws of some countries do not protect intellectual property rights to the same extent as U. S. laws, and those countries may lack adequate rules and procedures for defending our intellectual property rights. Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and / or applications will be due to be paid to the USPTO and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents and / or applications. We rely on our outside counsel and employ an outside firm to pay these fees due to USPTO and non- U. S. patent agencies. The USPTO and various non- U. S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. Although an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which non- compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors might be able to enter the market, which would have a material adverse effect on our business. If the patent applications we hold or have in- licensed with respect to our current and future research and development programs and product candidates fail to issue, if their validity, breadth or strength of protection is threatened, or if they fail to provide meaningful exclusivity for our technology or any products and product candidates that we or our collaborators develop, it could dissuade companies from collaborating with us to develop product candidates, encourage competitors to develop competing products or technologies and threaten our or our collaborators' ability to commercialize **our current and any** future product candidates. Any such outcome could have a material adverse

effect on our business. Our commercial success depends in part upon our ability to develop, manufacture, market and sell product candidates without alleged or actual infringement, misappropriation or other violation of the patents and proprietary rights of third parties. Litigation relating to infringement or misappropriation of patent and other intellectual property rights in the pharmaceutical and biotechnology field is common, including patent infringement lawsuits, and such interference, derivation, reexamination, post- grant review, inter parties review and opposition proceedings before the USPTO and corresponding international patent offices. The various markets in which we plan to operate are subject to frequent and extensive litigation regarding patents and other intellectual property rights. In addition, many companies in intellectual property-dependent industries, including the biotechnology and pharmaceutical industries, have employed intellectual property litigation as a means to gain an advantage over their competitors. Numerous United States, EU and other internationally issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we and our collaborators are developing product candidates. For example, we are aware of issued patents in the United States and certain foreign jurisdictions expiring in January 2034 that potentially cover certain **parts of the intellectual property included in CTIM- 76. As well, we are aware of a pending patent application in the United States and certain foreign jurisdictions that, if issued, would expire in 2042, and that potentially covers certain parts** of the intellectual property included in CTIM- 76. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our current and any future product candidates may be subject to claims of infringement of the intellectual property rights of third parties. As a result of any patent infringement claims, or in order to avoid any potential infringement claims, we may choose to seek, or be required to seek, a license from a third party, which may require payment of substantial royalties or fees, or require us to grant a cross-license under our intellectual property rights. These licenses may not be available on reasonable terms or at all. Even if a license can be obtained on reasonable terms, the rights may be nonexclusive, which would give our competitors access to the same intellectual property rights. If we are unable to enter into a license on acceptable terms, we or our collaborators could be prevented from commercializing one or more product candidates, forced to modify such product candidates, forced to cease some aspect of our business operations, or be required to pay substantial damages to a third party, which could harm our business significantly. We or our collaborators might also be forced to redesign or modify our technology or product candidates so that we no longer infringe the third- party intellectual property rights, which may result in significant cost or delay to us, or which redesign or modification could be impossible or technically infeasible. Even if we were ultimately to prevail, any of these events could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business. Further, if a patent infringement suit is brought against us, our collaborators or our third- party service providers, our development, manufacturing or sales activities relating to the product or product candidate that is the subject of the suit may be delayed or terminated. In addition, defending such claims may cause us to incur substantial expenses and, if successful, could cause us to pay substantial damages if we are found to be infringing a third- party' s patent rights. We may not have sufficient resources to bring these actions to a successful conclusion. These damages potentially include treble damages and attorneys' fees if we are found to have infringed such rights willfully. Some claimants may have substantially greater resources than we do and may be able to sustain the costs of complex intellectual property litigation to a greater degree and for longer periods of time than we could. In addition, patent holding companies that focus solely on extracting royalties and settlements by enforcing patent rights may target us. We may in the future be subject to third- party claims and similar adversarial proceedings or litigation in other jurisdictions regarding our infringement of the patent rights of third parties. Even if such claims are without merit, a court of competent jurisdiction could hold that these third- party patents are valid, enforceable and infringed, and the holders of any such patents may be able to block our or our collaborators' ability to further develop or commercialize the applicable product candidate unless we obtain a license under the applicable patents, or until such patents expire or are finally determined to be invalid or unenforceable. Similarly, if any third- party patents were held by a court of competent jurisdiction to cover aspects of our technologies, compositions, formulations, or methods of treatment, prevention or use, the holders of any such patents may be able to prohibit our use of those technologies, compositions, formulations, methods of treatment, prevention or use or other technologies, effectively blocking our or our collaborators' ability to develop and commercialize the applicable product candidate until such patent expires or is finally determined to be invalid or unenforceable or unless we or our collaborators obtain a license. Competitors may infringe our patents. In the event of infringement or unauthorized use, we may file one or more infringement lawsuits, which can be expensive and time- consuming. An adverse result in any such litigation proceedings could put one or more of our patents at risk of being invalidated, being found to be unenforceable, and / or being interpreted narrowly and could put our patent applications at risk of not issuing and / or could impact the validity or enforceability positions of our other patents. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. Some of our competitors may be able to sustain the costs of complex intellectual property litigation more effectively than we can because they have substantially greater resources. In addition, intellectual property litigation, regardless of its outcome, may cause negative publicity, adversely impact prospective customers, cause product shipment delays or prohibit us from manufacturing, marketing or otherwise commercializing our products, services and technology. Any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise additional funds or otherwise have a material adverse effect on our business, results of operation, financial condition or cash flows. We rely on patent protection as well as trademark, trade secret and other intellectual property rights protection and contractual restrictions to protect CTIM- 76, ~~ONA~~ **CT** - ~~XR~~ **95, CT- 202** and any future product candidates. Our commercial success depends upon obtaining and maintaining proprietary rights to our intellectual property estate, including rights relating to CTIM- 76, ~~ONA~~ **CT** - ~~XR~~ **95, CT- 202** and any future product candidates, as well as successfully defending these rights against third- party challenges and successfully enforcing these rights to prevent third- party infringement. We will only be able to protect CTIM- 76, ~~ONA~~ **CT** - ~~XR~~ **95, CT- 202** and any future product candidates from unauthorized use by third parties to the

extent that valid and enforceable patents or effectively protected trade secrets cover them. Our ability to obtain and maintain patent protection for CTIM- 76, ~~ONA-~~**CT** - ~~XR-~~**95, CT- 202** and any future product candidates is uncertain due to a number of factors, including the following factors: • we may not have been the first to invent the technology covered by our pending patent applications or issued patents; • we may not be the first to file patent applications covering product candidates, including their compositions or methods of use, as patent applications in the United States and most other countries are confidential for a period of time after filing; • others may identify prior art or other bases upon which to challenge and ultimately invalidate our patents or otherwise render them unenforceable; • our compositions and methods may not be patentable; • our disclosures in patent applications may not be sufficient to meet the statutory requirements for patentability; • any or all of our pending patent applications may not result in issued patents; • others may independently develop identical, similar or alternative technologies, products or compositions, or methods of use thereof; • others may design around our patent claims to produce competitive technologies or products that fall outside of the scope of our patents; • we may fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection; • we may not seek or obtain patent protection in countries and jurisdictions that may eventually provide us a significant business opportunity; • we may decide not to maintain or pursue patents and patent applications that, at some point in time, may cover our products, potential products, or product candidates; • any patents issued to us may not provide a basis for commercially viable products, may not provide any competitive advantages or may be successfully challenged by third parties; • our representatives or their agents may fail to apply for **or maintain** patents in a timely fashion; and • despite our efforts to enter into agreements with employees, consultants, collaborators, and advisors to confirm ownership and chain of title in patents and patent applications, an inventorship or ownership dispute could arise that may permit one or more third parties to practice our technologies or enforce our patent rights, including possible efforts to enforce patent rights against us. Even if we have or obtain patents covering CTIM- 76, ~~ONA-~~**CT** - ~~XR-~~**95, CT- 202** and any future product candidates or compositions, others may have filed, and in the future may file, patent applications covering compositions, products or methods that are similar or identical to ours, which could materially affect our ability to successfully develop a product candidate or to successfully commercialize any approved products alone or with collaborators. In addition, because patent applications can take many years to issue, there may be currently pending applications unknown to us that may later result in issued patents that may cover CTIM- 76, ~~ONA-~~**CT** - ~~XR-~~**95, CT- 202** or any future product candidates or compositions. These patent applications may have priority over patent applications filed by us. For example, we are aware of issued patents in the United States and certain foreign jurisdictions expiring in January 2034 that potentially cover certain **parts of the intellectual property included in CTIM- 76. As well, we are aware of a pending patent application in the United States and certain foreign jurisdictions that, if issued, would expire in 2042, and that potentially covers certain parts** of the intellectual property included in CTIM- 76. While we believe we will have reasonable defenses against any potential claim of infringement **, including challenging the validity of any such patents** , we may not be successful in such efforts, and we also may not be able to obtain a license to such patents on commercially reasonable terms, or at all. If such patent is valid and not yet expired when, and if, we receive marketing approval for CTIM- 76 we may need to seek a license to such patent, which may not be available on commercially reasonable terms or at all. Failure to receive a license to such patent, or other potentially relevant patents currently unknown to us, could delay the manufacture or commercialization of CTIM- 76 or require us to incur additional payments and expenses, including legal fees, court issued damages or settlement costs. The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or freedom to operate 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 the United States, the natural expiration of a patent is generally 20 years after it is filed. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. Without patent protection for current or any future product candidates, we may be open to competition from generic or biosimilar versions of such potential products. 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. 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 those we or our collaborators may develop. In addition, we also try to protect our trade secrets, know- how and other proprietary information through non- disclosure and confidentiality provisions in our agreements with parties who have access to them, such as our employees, consultants and research partners. Such agreements may not be enforceable or may not provide meaningful protection for our trade secrets, know- how and / or other proprietary information in the event of unauthorized uses or disclosure or other breaches of the provisions, and we may not be able to prevent such unauthorized uses or disclosure. Moreover, if a party having an agreement with us has an overlapping or conflicting obligation to a third party, our rights in and to certain intellectual property could be undermined. Monitoring unauthorized and inadvertent disclosure and uses is difficult, and we do not know whether the steps we have taken to prevent such disclosure and uses are, or will be, adequate. In addition, monitoring unauthorized disclosure and uses of our trade secrets is difficult, and we do not know whether the steps we have taken to prevent such disclosure and uses are, or will be, adequate. If we were to enforce a claim that a third party had illegally obtained and was using our trade secrets, it would be expensive and time- consuming, and the outcome would be unpredictable, and any remedy may be inadequate. In addition, courts outside the United States may be less willing to protect trade secrets. We rely on trade secrets to protect our proprietary technologies, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. We rely in part on confidentiality agreements with our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to protect our trade secrets and other proprietary information. These agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the

event of unauthorized disclosure of confidential information. In addition, others may independently discover our trade secrets and proprietary information. Costly and time- consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and failure to obtain or maintain trade secret protection could adversely affect our competitive business position. Because we ~~may~~ rely on third parties to manufacture our ~~potential~~ product candidates, and because we collaborate with various organizations and academic institutions on the advancement of our current and potential product candidates, we must, at times, 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, collaborative research agreements, consulting agreements or other similar agreements with our manufacturers, collaborators, advisors, employees 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, such as 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, are used inappropriately to create new inventions 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 discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may have a material adverse effect on our business. We are a party to intellectual property license agreements that are important to our business and expect to enter into additional license agreements in the future. Our existing license agreements impose, and we expect that future license agreements will impose, various diligence, milestone payment, royalty and other obligations on us. Additionally, we may need to outsource and rely on third parties for many aspects of the development, sales and marketing of any products covered under our current and future license agreements. Delay or failure by these third parties could adversely affect the continuation of our license agreements with our licensors. If we fail to comply with any of our obligations under these agreements, or we are subject to a bankruptcy, our licensors may have the right to terminate the license, in which event we would not be able to market any products covered by the license. In some cases, patent prosecution of our licensed technology is controlled solely by the licensor. If such licensor fails to obtain and maintain patent or other protection for the proprietary intellectual property we license from such licensor, we could lose our rights to such intellectual property or the exclusivity of such rights, and our competitors could market competing products using such intellectual property. In that event, we may be required to expend significant time and resources to develop or license replacement technology. Additionally, if such licensor fails to have patent rights that they otherwise may claim to have for the proprietary intellectual property we license from such licensor or they infringe the intellectual property rights of a third party, it could delay or materially impact our ability to commercialize our product candidates that rely on such intellectual property. In that event, we may be required to expend significant time and resources to develop or license replacement technology, to address any infringement claims that may be made by such third party, and to compensate a third party for any infringement. If we are unable to develop or license replacement technology, we or our collaborators may be unable to develop or commercialize the affected product candidates, which could harm our business significantly. In other cases, we control the prosecution of patents resulting from licensed technology. In the event we breach any of our obligations related to such prosecution, we may incur significant liability to our licensing partners. Licensing of intellectual property is of critical importance to our business and involves complex legal, business and scientific issues and is complicated by the rapid pace of scientific discovery in our industry. Disputes may arise regarding intellectual property subject to a licensing agreement, including: • the scope of rights granted under the license agreement and other interpretation- related issues; • the extent to which our technology and processes infringe intellectual property of the licensor or a third party that is not subject to the licensing agreement; • the extent to which the licensed intellectual property may infringe the intellectual property of a third party that is not subject to the licensing agreement, as well as the licensor' s potential breach of its related warranties or obligations in a licensing agreement; • the sublicensing of patent and other rights under our collaborative development relationships; • our diligence obligations under the license agreement and what activities satisfy those diligence obligations; • the ownership of inventions and know- how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and • the priority of invention of patented technology. If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates. If we do not obtain patent term extension in the United States under the Hatch- Waxman Act and in foreign countries under similar legislation with respect to our current and any future product candidates, thereby potentially extending the term of marketing exclusivity for such 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 current and any future 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, or 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. In the European Union, our current and any future 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. Filing, prosecuting and defending patents on our current and any future product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property

rights in some countries outside the United States can be less extensive than those in the United States. 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. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. Changes in U. S. patent law, and the laws of other countries, could diminish the value of patents in general, thereby impairing our ability to protect our products. The United States has enacted, and continues to consider, wide- ranging patent reform legislation. Recent U. S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U. S. Congress, the federal courts, the USPTO, and the courts and regulatory agencies 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. The market price for our common stock is likely to be volatile, in part because our shares have been traded publicly for **only** a ~~short time~~ **few years** . In addition, the market price of our common stock **has and** may **continue to** fluctuate significantly in response to several factors, most of which we cannot control, including: • quarterly variations in our operating results compared to market expectations; • adverse publicity about us, the industries we participate in or individual scandals; • announcements of new offerings or significant price reductions by us or our competitors; • stock price performance of our competitors; • fluctuations in stock market prices and **volumes; • large purchases or sales causing stock price fluctuations due to low trading** volumes; • changes in senior management or key personnel; • changes in financial estimates by securities analysts; • the market' s reaction to our reduced disclosure as a result of being an " emerging growth company " under the JOBS Act; • negative earnings or other announcements by us or our competitors; • defaults on indebtedness, incurrence of additional indebtedness, or issuances of additional capital stock; • global economic, legal and regulatory factors unrelated to our performance; and • the other factors listed in this " Risk Factors " section. Volatility in the market price of our common stock may prevent investors from being able to sell their shares at or above their purchase price. As a result, you may suffer a loss on your investment. Our common stock is listed on The Nasdaq Stock Market. In order to maintain that listing, we must satisfy minimum financial and other requirements including, without limitation, a requirement that our closing bid price be at least $ 1. 00 per share. On ~~January 24~~ **February 27** , ~~2023~~ **2025 ,** we received a letter from Nasdaq stating that **the** we were not in compliance with Nasdaq Listing Rule 5550 (a) (2) (the " Minimum Bid Price Rule ") because our common stock failed to maintain a minimum closing bid price of $ 1. 00 per share for 30 consecutive business days. This letter ~~provided~~ **provides** an initial 180 calendar day period, or until ~~July 24~~ **August 26** , ~~2023~~ **2025** , in which to regain compliance. **We may request stockholder approval to undergo** ~~On June 15, 2023, we received~~ a ~~letter (the "~~ **reverse stock split in order to regain** ~~Compliance~~ **compliance with** ~~Letter ") from Nasdaq notifying us that, for~~ the **$ 1. 00** ~~prior ten consecutive business days, the~~ closing bid price **requirement** ~~of our common stock had been at $ 1~~ . **If** ~~00 per share or greater and that~~ we ~~had~~ **do not** ~~regained~~ -- **regain** compliance ~~with the Minimum Bid Price Rule~~ **by August 26, 2025, we may be eligible for an additional 180- day grace period** . If we fail to **regain and** maintain compliance with the Minimum Bid Price Rule or we fail to continue to meet all other applicable continued listing requirements for The Nasdaq Stock Market, our common stock may be delisted, which would adversely affect the market liquidity of our common stock and our ability to obtain financing to fund our operations. If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, the market price for the shares 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. If research analysts do not establish and maintain adequate research coverage or if one or more of the analysts who covers us downgrades our common stock or publishes inaccurate or unfavorable research about our business, the market price for our common stock would likely decline. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, we could lose visibility in the financial markets, which, in turn, could cause the market price or trading volume for our common stock to decline. We do not expect to pay dividends in the foreseeable future, and you must rely on price appreciation of your shares for return on your investment. We have paid no cash dividends on any class of our stock to date, and we do not anticipate paying cash dividends in the near term. For the foreseeable future, we intend to retain any earnings to finance the development and expansion of our business, and we do not anticipate paying any cash dividends on our stock. Accordingly, investors must be prepared to rely on sales of their shares after price appreciation to earn an investment return, which may never occur. Investors seeking cash dividends should not purchase our shares. Any determination to pay dividends in the future will be made at the discretion of our

board of directors and will depend on our results of operations, financial condition, contractual restrictions, restrictions imposed by applicable law and other factors our board deems relevant. In the future, we may attempt to increase our capital resources by entering into debt or debt- like financing that is secured by all or up to all of our assets, or issuing debt or equity securities, which could include issuances of commercial paper, medium- term notes, senior notes, subordinated notes or shares. In the event of our liquidation, our lenders and holders of our debt securities would receive a distribution of our available assets before distributions to our stockholders. In addition, any preferred stock, if issued by our company, may have a preference with respect to distributions and upon liquidation, which could further limit our ability to make distributions to our stockholders. Because our decision to incur debt and issue securities in our future offerings will depend on market conditions and other factors beyond our control, we cannot predict or estimate the amount, timing or nature of our future offerings and debt financing. Further, market conditions could require us to accept less favorable terms for the issuance of our securities in the future. Thus, you will bear the risk of our future offerings reducing the value of your common stock and diluting your interest in our company. FINRA sales practice requirements may limit a stockholder' s ability to buy and sell our common stock. The Financial Industry Regulatory Authority (" FINRA ") has adopted rules requiring that, in recommending an investment to a customer, a broker- dealer must have reasonable grounds for believing that the investment is suitable for that customer. Prior to recommending speculative or low- priced securities to their non- institutional customers, broker- dealers must make reasonable efforts to obtain information about the customer' s financial status, tax status, investment objectives and other information. Under interpretations of these rules, FINRA has indicated its belief that there is a high probability that speculative or low- priced securities will not be suitable for at least some customers. If these FINRA requirements are applicable to us or our securities, they may make it more difficult for broker- dealers to recommend that at least some of their customers buy our common stock, which may limit the ability of our stockholders to buy and sell our common stock and could have an adverse effect on the market for and price of our common stock. We are subject to ongoing public reporting requirements that are less rigorous than Exchange Act rules for companies that are not emerging growth companies and our stockholders could receive less information than they might expect to receive from more mature public companies. We are required to publicly report on an ongoing basis as an " emerging growth company " (as defined in the JOBS Act) under the reporting rules set forth under the Exchange Act. For so long as we remain an emerging growth company, we may take advantage of certain exemptions from various reporting requirements that are applicable to other Exchange Act reporting companies that are not emerging growth companies, including but not limited to: • not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes- Oxley Act; • being permitted to comply with reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements; and • being exempt from the requirement to hold a non- binding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. In addition, Section 107 of the JOBS Act also provides that an emerging growth company can take advantage of the extended transition period provided in Section 7 (a) (2) (B) of the Securities Act for complying with new or revised accounting standards. In other words, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to take advantage of the benefits of this extended transition period. Our financial statements may therefore not be comparable to those of companies that comply with such new or revised accounting standards. We expect to take advantage of these reporting exemptions until we are no longer an emerging growth company. We will remain an emerging growth company until October 19, 2026, although if the market value of our common stock that is held by non- affiliates exceeds $ 700 million as of any June 30 before that time, we would cease to be an emerging growth company as of the following December 31. Because we are subject to ongoing public reporting requirements that are less rigorous than Exchange Act rules for companies that are not emerging growth companies, our stockholders could receive less information than they might expect to receive from more mature public companies. We cannot determinate if investors find our common stock less attractive because we elect to rely on these exemptions, or if taking advantage of these exemptions has or will result in less active trading or more volatility in the price of our common stock. If we fail to maintain effective internal control over financial reporting and effective disclosure controls and procedures, we may not be able to accurately report our financial results in a timely manner or prevent fraud, which may adversely affect investor confidence in our company. We are subject to the reporting requirements of the Exchange Act, as well as the Sarbanes- Oxley Act and the rules and regulations of the stock market on which our common stock is listed. We are required, pursuant to Section 404 of the Sarbanes- Oxley Act, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting. This assessment includes disclosure of any material weaknesses identified by our management in our internal control over financial reporting. In addition, our independent registered public accounting firm will be required to attest to the effectiveness of our internal control over financial reporting in our first annual report required to be filed with the SEC following the date we are no longer an emerging growth company if we are not a non- accelerated filer at such time. If we or our independent registered public accounting firm determines we have a material weakness in our internal control over financial reporting, investors could lose confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by the SEC or other regulatory authorities. Failure to remedy any material weakness or significant deficiency in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets. Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity and / or debt financings, partnerships and collaborations, licensing agreements or other strategic arrangements. To the extent that we raise additional capital or pay expenses through the sale or issuance of equity or convertible debt securities, your ownership interest will be diluted, and the terms of such securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. To the extent that we raise additional capital through debt financing, it would result in increased fixed payment obligations and a portion of our operating cash flows, if any, being dedicated to the payment of principal and interest on such indebtedness. In addition, debt

financing may involve agreements that include restrictive covenants that impose operating restrictions, such as restrictions on the incurrence of additional debt, the making of certain capital expenditures or the declaration of dividends. To the extent we raise additional capital through arrangements with collaborators or otherwise, we may be required to relinquish some of our technologies, research programs, product development activities, product candidates and / or future revenue streams, license our technologies and / or product candidates on unfavorable terms or otherwise agree to terms unfavorable to us. Furthermore, any capital raising efforts may divert our management from their day- to- day activities, which may adversely affect our ability to advance research programs, product development activities or current or future product candidates. General Risk Factors We incur increased costs as a result of being a public company and in the administration of our organizational structure. As a public company, we have incurred significant legal, accounting, insurance, and other expenses, including costs associated with public company reporting requirements. We also have incurred and will **continue to** incur costs associated with the Sarbanes- Oxley Act and related rules implemented by the SEC and ongoing periodic expenses in connection with the administration of our organizational structure. These laws and regulations could make it more difficult or costly for us to obtain certain types of insurance, including director and officer liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. These laws and regulations could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as our executive officers. Furthermore, if we are unable to satisfy our obligations as a public company, we could be subject to delisting of our common stock, fines, sanctions and other regulatory action and potentially civil litigation. We are subject to complex tax rules relating to our business, and any audits, investigations or tax proceedings could have a material adverse effect on our business, results of operations and financial condition. We are subject to income and non- income taxes in the United States and Ireland, as well as the tax laws and regulations related to such matters. Tax accounting and compliance often involves complex issues, and judgment and interpretation is required in determining our provision for income taxes and other tax liabilities as well as the application of tax laws and regulations. We could become subject to income and non- income taxes in non- U. S. jurisdictions other than Ireland as well. In addition, many jurisdictions have detailed transfer pricing rules, which require that all transactions with related parties be priced using arm' s length pricing principles within the meaning of such rules. The application of such transfer pricing rules, as well as of withholding taxes, goods and services taxes, sales taxes and other taxes is not always clear and we may be subject to tax audits relating to such rules or taxes. We ~~believe that our tax positions are reasonable, and our tax provisions and reserves are adequate to cover any potential liability. We~~ are also currently not subject to any tax audits. However, various items cannot be accurately forecasted and future events may be treated as discrete to the period in which they occur. In addition, the Internal Revenue Service or other taxing authorities may disagree with our positions. Furthermore, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us (possibly with retroactive effect). If the Internal Revenue Service or any other tax authorities were successful in challenging our positions, or existing tax laws, statutes, rules, regulations or ordinances are so interpreted, changed or modified, we may be liable for additional tax and penalties and interest related thereto or other taxes, as applicable, in excess of any reserves established therefor, which may have a significant impact on our results and operations and future cash flow. Our business and operations would suffer in the event of system failures or security breaches. Our computer systems, as well as those of third parties with which we have relationships, are vulnerable to damage from computer viruses, unauthorized access, natural and manmade disasters, terrorism, war and telecommunication and electrical failures. If we or a third party with which we have relationships were to experience a system failure, accident or security breach, such an event could cause interruptions in our or their operations, or it could result in delays and / or material disruptions of our research and development programs. For example, the loss of trial data from completed, ongoing or planned trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of or damage to data or applications, or inappropriate disclosure of personal, confidential or proprietary information, we could incur liability and the development of our current and any future product candidates could be delayed. The U. S. federal and various state and foreign governments have enacted or proposed requirements regarding the collection, distribution, use, security and storage of personally identifiable information and other data relating to individuals, and U. S. federal and state consumer protection laws are being applied to enforce regulations related to the online collection, use and dissemination of data. In the ordinary course of our business, we and third parties with which we have relationships collect and store sensitive data, including intellectual property, clinical trial data, proprietary business information, personal data and personally identifiable information of our clinical trial subjects and employees, consultants and contractors, in data centers and on networks. The secure processing, maintenance and transmission of this information is critical to our operations. Despite our and our collaborators' security measures, our information technology and infrastructure may be vulnerable to attacks by hackers or internal bad actors, breaches due to employee error, technical vulnerabilities, malfeasance or other disruptions, and any such breach could compromise our or their networks and the information stored there could be accessed, publicly disclosed, lost or stolen. Any such access, disclosure, notifications, follow- up actions related to such a security breach or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information and significant costs, including regulatory penalties, fines and legal expenses, and such an event could disrupt our operations, cause us to incur remediation costs, damage our reputation and cause a loss of confidence in us and our collaborators' ability to conduct clinical trials, which could adversely affect our reputation and delay our research and development programs. We or third parties with whom we have relationships may be adversely affected by natural or manmade disasters, and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster. Natural or manmade disasters could severely disrupt our operations and have a material adverse effect on our business, results of operations, financial condition and prospects. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our facilities, that damaged our infrastructure or that otherwise disrupted operations, it may be difficult or, in certain cases,

impossible for us to continue our business for a substantial period of time, and our research and development activities could be setback or delayed. The disaster recovery and business continuity plan (s) we have in place may prove inadequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which could have a material adverse effect on our business, and such an event could disrupt our operations, cause us to incur remediation costs, damage our reputation and cause a loss of confidence in us and our or third parties' ability to conduct clinical trials, which could adversely affect our reputation and delay our research and development programs. We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties or that our employees have wrongfully used or disclosed alleged trade secrets of their former employers. We may now and in the future employ individuals who were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of any of our employees' former employers or other third parties. 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, which could adversely impact 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 and consultants. We could be subject to securities class action litigation. In the past, securities class action litigation has often been brought against companies following a decline in the market price of their securities. This risk is especially relevant for us because biotechnology companies have experienced significant share 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. ~~51~~