Risk Factors Comparison 2025-03-06 to 2024-03-21 Form: 10-K

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

Risks Related to Our Financial Position and Need for Additional Capital ● We have a limited operating history and no products approved for commercial sale. We have a history of significant losses, expect to continue to incur significant losses for the foreseeable future and may never achieve or maintain profitability. We have never generated revenue from product sales and may never be profitable. ● We will require substantial additional financing to pursue our business objectives, which may not be available on acceptable terms, or at all. Risks Related to the Discovery and Development of Our Product Candidates ● Our business is dependent on our ability to advance our current and future product candidates through preclinical studies and clinical trials, marketing approval and ultimately commercialization, each of which is uncertain. ● Regulatory approval processes are lengthy and inherently unpredictable. ● Clinical development involves a lengthy and expensive process with uncertain outcomes, and as an organization we have limited experience designing and implementing clinical trials. Failure to adequately design a trial, or incorrect assumptions about the design of the trial, could result in delays in product development and in additional costs, delays or the inability to develop, obtain regulatory approval for or commercialize our products. ● Preclinical development is uncertain. Our preclinical programs may experience delays or may never advance to clinical trials, which would adversely affect our ability to obtain regulatory approvals or commercialize these programs on a timely basis or at all. ● Initial positive trial results and positive results from preclinical studies and early- stage clinical trials may not be predictive or indicative of results obtained when the trial is completed or in later stage trials. ● We, or our collaborators, could encounter difficulties enrolling patients in our clinical trials due to pandemics or other factors. ● Because the numbers of subjects in our Phase 1 ~~/ 2 and Phase 1~~ clinical ~~trials~~ **trial** are small, the results from ~~each of these~~ **the** ~~trials~~ **trial**, once completed, may be less reliable than results achieved in larger clinical trials. ● Our current or future product candidates may cause undesirable side effects or have other properties that could halt their clinical development, delay or prevent their regulatory approval, limit their commercial potential or result in significant negative consequences. Risks Related to the Regulatory Approval and Commercialization of Product Candidates and Other Legal Compliance Matters ● We may be unable to obtain regulatory approval of our product candidates. The denial or delay of any such approval would prevent or delay commercialization of our product candidates and harm our business. ● Even if a current or future product candidate receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third- party payors and others in the medical community necessary for commercial success, and the market opportunities for any such product candidate may be limited. ● We are studying and developing product candidates in combination with other therapies, which exposes us to additional regulatory risks. ● We depend on data and our information technology systems, and any failure of these systems or any related security breaches, loss of data, or other disruptions could harm our business. Risks Related to Manufacturing ● Given our limited operating history, our manufacturing experience, as an organization and with our manufacturing facility, is limited. ● We may be unable to secure sufficient quantities of our product candidates economically, or at the necessary scale, whether through use of a third party, by scaling up our paused manufacturing operations, or by otherwise failing to source adequate supply of our product candidates which would delay or prevent us from developing and, if approved, commercializing our product candidates. ● We are subject to multiple manufacturing risks, any of which could substantially increase our costs and limit supply of our product candidates. ● We depend on third- party suppliers for key materials used in our manufacturing process, and the loss of these third- party suppliers, their inability to comply with applicable regulatory requirements, or their inability to supply us with adequate materials could harm our business. Risks Related to Intellectual Property ● We have filed patent applications for our product candidates, but we have to- date obtained only a small number of patents from these applications. If we are unable to obtain and maintain patent protection, or if the scope of the patent protection obtained is not sufficiently robust, our competitors could develop and commercialize products similar or identical to ours, and our ability to successfully commercialize our product candidates may be adversely affected. ● We are party to a license agreement with Yale University under which we acquired rights to intellectual property related to certain of our product candidates. If we breach our obligations under this agreement, the agreement could be terminated, which would adversely affect our business and prospects. ● Our intellectual property agreements with third parties may be subject to disagreements over contract interpretation, which could narrow the scope of our rights to the relevant intellectual property or technology or increase our financial or other obligations to our licensors. ● We may not be able to protect our intellectual property rights throughout the world. ● We may be subject to claims, or we may become involved in lawsuits to protect or enforce our intellectual property, which could be expensive, time- consuming and unsuccessful; our intellectual property could be found invalid or unenforceable. Risks Related to Reliance on Third Parties ● We rely on third parties to help conduct our ongoing and planned preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties, comply with regulatory requirements or meet expected deadlines, we may not be able to obtain marketing approval for our product candidates. ● We may depend on other third- party collaborators for the discovery, development and commercialization of certain of our current and future product candidates. If our collaborations are not successful, we may not be able to capitalize on the market potential of these product candidates. ● We may seek to establish additional collaborations and, if we are not able to establish them on commercially reasonable terms, we may have to alter our development and commercialization plans. Risks Related to Our Business ● We are highly dependent on our key personnel, and if we are not successful in attracting, motivating and retaining highly qualified personnel, we may not be able to successfully implement our business strategy. ● We face significant competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively. ● In the future, we may need to grow the size of our

organization, and we may experience difficulties in managing this growth. ● If we are unable to establish marketing, sales and distribution capabilities for any product candidate that may receive regulatory approval, we may not be successful in commercializing those product candidates. Risks Related to Our Common Stock ● The price of our common stock has been and may in the future be volatile and fluctuate substantially **. ● We are currently not in compliance with the continued listing standards of the Nasdaq Global Select Market, and if we are unable to regain compliance, our common stock will be delisted from the exchange** . ● We have been and may in the future be subject to securities litigation, which can be expensive and could divert management' s attention. ● If securities analysts do not publish research or reports about our business or if they publish inaccurate or unfavorable research about our business, the price of our stock could decline. ● Sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall, even if our business is doing well. 5PART I Item 1. BusinessOverviewWe are a clinical- stage biopharmaceutical company that is focused on advancing innovative medicines that treat cancer patients that do not respond to, or **that** have disease progression on ~~,~~current therapies, through the use of differentiated mechanisms of actions including Antibody- Drug Conjugates (**"** ADCs **"**) ~~, antibodies and proteins~~ . We focus on advancing therapies that leverage our core strengths in understanding biological pathways and biomarkers, the interactions of cells, including in the tumor microenvironment, and the role each interaction plays in a biologic response. ~~We are focusing on~~ **Since inception, we have devoted substantially all of** our ~~highest- value~~ **efforts and financial resources to discovery, research and development activities for our product candidates, identifying business development** opportunities ~~: i) NC410~~ , **raising capital** ~~a LAIR- 2 fusion protein that, in combination with pembrolizumab, demonstrated early evidence of clinical activity in colorectal (CRC)~~ and ~~ovarian cancers~~ **securing intellectual property rights related to our product candidates** . **Our product candidate** ~~We expect several potential catalysts in 2024. ii)~~ LNCB74 ~~, an ADC that is directed to B7- H4, a clinically validated cancer target. Given our internal expertise of B7- H4 coupled with LegoChem Biosciences, Inc' s (LegoChem) ADC technology, we plan for an Investigational New Drug application (IND) in 2024. In March 2024, we announced a prioritization and restructuring of our operations to align with our focused pipeline. We are pausing our internal manufacturing operations and reducing our workforce. In addition, we are seeking to partner our clinical programs NC525 and NC318 and our preclinical non- oncology programs NC605, for chronic bone diseases, and NC181, for Alzheimer' s disease. We project these actions will extend our cash runway into the second half of 2026. Our StrategyThe crucial elements of our business strategy include the following: ● Advancing development of NC410 in combination with pembrolizumab (NC410 Combo) based on early evidence of clinical activity. ● Based on emerging Phase 1b results in ovarian cancer, where NC410 Combo demonstrated an overall response rate (ORR) of 42. 8 % at the 9- week scan based on 7 evaluable patients, we are in the process of enrolling approximately 18 additional patients in this clinical trial. We plan to present the data from approximately 25 ovarian cancer patients in the second half of 2024. ● Based on initial Phase 1b results in CRC, where Standard of Care (SOC) has historically shown limited efficacy and short median progression- free survival (mPFS), we have completed enrollment of an additional 20 patients with the objective of confirming and enhancing the 10. 5 % ORR seen in the initial 100 mg cohort of 19 evaluable patients. We plan to provide data on CRC in the second quarter of 2024. ● Accelerating development of LNCB74, a differentiated ADC focused on B7- H4, a clinically validated target. Building on our strong know- how and previous clinical experience with B7- H4, we have created a new mAb intermediate and combined it with LegoChem' s differentiated ADC technology to create a promising B7- H4 ADC for the treatment of B7- H4 expressing cancers. We plan to file an IND application by year- end 2024. ● Pursuing partnering of our clinical oncology programs NC525 and NC318 and our non- oncology preclinical programs. Based on our focused and prioritized pipeline, we will seek partnering, licensing, or other strategic approaches for our NC525 and NC318 programs. We also have two novel preclinical candidates, one in the area of chronic bone diseases and the orphan indication for Osteogenesis Imperfecta (OI), and one for the neurodegenerative Alzheimer' s disease, both of which could be IND- ready in the first half of 2025. We will continue to seek partners or other strategic approaches to advance these programs. 6Our Fusion Protein Product Candidate: NC410 NC410 is a fusion protein of LAIR- 2, a naturally occurring soluble version of, and decoy protein for, LAIR- 1 that is designed to block immune suppression mediated by LAIR- 1. Early preclinical correlative biomarker work suggests that NC410 has the potential to overcome tumor resistance by remodeling the tumor' s extracellular matrix (ECM) to remove a physical barrier surrounding the tumor to enhance T cell tumor killing. We have exclusive worldwide rights to NC410. Mechanism of action The rationale for moving into a combination trial for NC410 is based on the mechanism of action of NC410, as seen in preclinical modeling and also during the NC410 monotherapy Phase 1 dose escalation study readouts. It has been shown that elevated collagen levels in the ECM, the tissue matrix surrounding the tumor, are associated with resistance to PD- 1 and PD- L1 therapies. In non- clinical colorectal models and early- stage monotherapy clinical studies conducted by NextCure, we have demonstrated that NC410 can remodel collagen in the ECM, which enhances T cell infiltration into the tumor. Collagen Buildup and Density Lead to Resistance ECM Remodeling Leads to Greater Anti- Tumor Function Tumor cells proliferate and become resistant T cells kill the tumor This results in immune activation, enhanced immune function in the TME and enhances anti- PD- 1 activity in multiple preclinical tumors models. We believe that this may translate to improved responses in patients with immune checkpoint naïve solid tumors. Our Clinical Development Plan for NC410We are currently conducting a Phase 1b / 2 clinical trial to evaluate NC410 in combination with KEYTRUDA ® (pembrolizumab), Merck & Co., Inc.' s (Merck) anti- PD- 1 therapeutic. We entered into a supply agreement for KEYTRUDA with Merck (known as MSD outside the United States and Canada) for the trial. Based on clinical responses and biomarker observations, we are focused on ovarian cancer and CRC patients who are immune checkpoint inhibitor (ICI) naïve. The combination has been shown to be well tolerated up to 200 mg of NC410 with Grade 3 or higher Treatment Related Adverse Events of 3. 7 %. 7Ovarian CancerIn March 2024, we announced evidence of early clinical activity and biomarker observations supporting the proposed mechanism of action for NC410 Combo in relapse / refractory ICI naïve ovarian cancer, with / without active liver metastasis, in 100 mg, and 200 mg cohorts. At data cutoff, there were 7 evaluable patients in these initial cohorts. Given that this data set is relatively early and a small number, in March 2024 we commenced~~

~~enrolling an additional 18 patients among the 100 mg and 200 mg cohorts. As of February 23, 2024, the findings of the initial 7 evaluable patients are summarized based on the FDA' s Response evaluation criteria in solid tumors (RECIST) 1. 1 guideline in the table below: Relapsed / Refractory ICI Naïve Ovarian Cancer, 100 mg & 200 mg cohortsEvaluable Patients as of February 23, 2024n = 7Overall Response Rate (ORR) 42. 8 %, n = 3Disease Control Rate (DCR) 42. 8 %, n = 3Evidence supporting mechanism of actionObserved in biomarker dataFrom the NC410 Combo Phase 1b patient data (n = 7) set as of the cutoff date: ● 3 partial responses (PR) were observed at the initial 9- week scan. ● 1 confirmed PR observed in the 200 mg cohort continues on study beyond 6 months. ● The 2 PRs at the 100 mg cohort are pending confirmatory scans at week 18. Biomarker data on blood samples drawn from patients in both the NC410 monotherapy trial and the NC410 combo trial support our hypothesis regarding the mechanism of action (MOA) and activity in PR patients as follows: ● Decrease in peripheral Granzyme B- expressing CD8 T cells, which supports our belief of our MOA that NC410 remodels the ECM and allows activated immune cells to infiltrate into the Tumor Microenvironment (TME). Generation of Collagen- derived product (CDP) 4GZ fragments is mediated by Granzyme B- expressing T cells and provides direct evidence of ECM remodeling and correlates with responses. ● Decrease in peripheral Myeloid- Derived Suppressor Cells reduces suppressive effects and enhances activation of immune cells and anti- tumor activity. ● Decrease in peripheral CCR7 DC T cells consistent with chemokine guided migration of immune cells to the TME. Taken together, the data demonstrate that NC410 plays a key role in mediating activation of immune cells and migration to TME through remodeling of the ECM. We believe NC410 Combo results in anti- tumor activity and clinical responses in patients that are shown to respond poorly to or are resistant to checkpoint inhibitors. Response rates using ICI therapy, both in mono and combo, in high- grade serous ovarian cancer (HGSOC) are historically low at under 10 % ORR with a mPFS of approximately 2 months. Given HGSOC is the most common type of ovarian cancer, we believe an opportunity exists for a clinical path forward in ovarian cancer. We plan to present the data from the ovarian cancer patients in the second half of 2024. CRCIn December 2023, we announced that given preliminary anti- tumor activity, additional patients would be added to the 100 mg cohort of patients with microsatellite stable (MSS) / microsatellite instable- low (MSI- L) immune checkpoint 8inhibitor (ICI) naïve CRC without active liver metastasis (LM-). There are 19 evaluable patients in this initial cohort and we completed enrollment of an additional 20 patients in January 2024. As of February 23, 2024, of the initial 19 evaluable patients, findings are summarized based on RECIST 1. 1 guideline in the table below: MSS / MSI- L ICI Naïve CRC, LM-, 100 mg cohortEvaluable Patients as of February 23, 2024n = 19Overall Response Rate (ORR) 10. 5 %, n = 2Disease Control Rate (DCR) 47. 3 %, n = 9Median Progression Free Survival (mPFS) 8. 1 monthsFrom the NC410 combo Phase 1b 19 patient data set as of the cutoff date: ● All responses were observed at the initial 9- week scan in the 100 mg cohort. ● Subjects enrolled had a median of 5 lines of prior treatment. ● The two responders remain as PRs, and continue on study for over 10 months and 5 months, respectively. We plan to present the data of the CRC patients in the 100 mg cohort who are MSS / MSI- L ICI Naïve CRC at a scientific conference in the second quarter of 2024. The CRC MSS / MSI- L population is extremely difficult to treat with most agents, including pembrolizumab, showing low single- digit response rates along with a limited mPFS. We believe if we can confirm and enhance the data observed in our initial findings of 19 patients, an opportunity exists for a clinical path forward that will improve the current standard of care. Our ADC Product Candidate: LNCB74LNCB74~~ is designed as a state- of- the- art B7- H4 targeted ADC to kill tumors. An ADC consists of a monoclonal antibody ~~(mAb)~~ conjugated to a cytotoxic drug via a chemical linker. B7- H4, a clinically validated target, is a cell surface protein expressed on multiple tumor types including breast, ovarian ~~,~~ and endometrial cancers, that we believe represents a **large market opportunity. We believe LNCB74 will be positioned as a promising B7- H4 ADC with both potential improved safety and efficacy compared to other ADCs targeting B7- H4. Preclinical studies demonstrated potent tumor killing in disease models and a favorable safety profile. LNCB74 is being advanced under a November 2022 Research Collaboration and Co- Development Agreement (the " LigaChem Agreement ") with LigaChem Biosciences, Inc. formerly known as LegoChem Biosciences, Inc., or (" LigaChem "). In December 2024, we announced that the U. S. Food and Drug Administration (the " FDA ") accepted an Investigational New Drug (" IND ") application for initiation of a Phase 1 clinical trial to evaluate LNCB74 for treating multiple cancers known to have high B7- H4 expression. We announced in January 2025 that the first patient had been dosed in our Phase 1 trial of LNCB74, and we are currently within cohort 2 of the dose escalation portion of the Phase 1 trial, enrolling patients with various tumor types, including breast, ovarian, and endometrial cancers. In addition, we are seeking to partner our other clinical programs NC410 and NC525 and pursue partners or third- party financing to advance our preclinical non- oncology programs: NC605 for chronic bone diseases; and NC181 for Alzheimer' s disease. Our StrategyThe crucial elements of our business strategy include the following: ● Accelerating development of LNCB74, a differentiated ADC focused on B7- H4, a clinically validated target. Building on our strong know- how and previous clinical experience with B7- H4, we have created a new mAb intermediate and combined it with LigaChem' s differentiated ADC technology to create a promising B7- H4 ADC for the treatment of B7- H4 expressing cancers. We are currently in cohort 2 of the dose escalation portion of the Phase 1 trial. We plan to initiate backfill cohorts in the second half of 2025. ● Pursuing partnering of our clinical oncology programs NC410 and NC525 as well as our non- oncology preclinical programs. Based on our focus on LNCB74, we will seek partnering, licensing or other strategic approaches for our NC410 and NC525 programs. Our non- oncology programs include NC181, a humanized antibody targeting ApoE4 for the treatment of Alzheimer' s disease, and NC605, an antibody that targets Siglec- 15 for the treatment of osteogenesis imperfecta. We believe that both of these non- oncology programs have the potential to file an IND application within 12 to 18 months if financial support from partners or third parties is secured. Our ADC Product Candidate: LNCB74LNCB74 is designed as a state- of- the- art B7- H4 targeted ADC to kill tumors. An ADC consists of a monoclonal antibody (mAb) conjugated to a cytotoxic drug via a chemical linker. B7- H4, a clinically validated target, is a cell surface protein expressed on multiple tumor types including breast, ovarian, and endometrial cancers, that we believe represents 6a** large market opportunity. LNCB74 will

be positioned as a promising B7- H4 ADC with both improved safety and efficacy based on the following differentiation: Antibody – B7- H4 mAb with an Fc modification to protect immune cells to improve safety. Linker – Cancer- selective payload release via a glucuronidase cleavage that minimizes toxicity in non- tumor cells. Payload – A Monomethyl auristatin E (MMAE) toxin in a drug- to- antibody ratio (DAR) of 4 and has the advantage to diffuse from the target cell and into surrounding tumor cells for bystander killing. **In December 2024, we announced that the FDA accepted the IND application and we are currently in cohort 2 of the dose escalation portion of the Phase 1 trial in patients with various tumor types, including breast, ovarian, and endometrial cancers. We plan to initiate backfill cohorts in the second half of 2025.** LNCB74 is being advanced under **the LigaChem** ~~a November 2022 Research Collaboration and Co- Development~~ Agreement **pursuant to** ~~(" LegoChem Agreement ") with LegoChem in~~ which both parties equally share the costs of ~~developing~~ **development** and profits. In April 2023, the parties designated LNCB74 as the first of up to three co- development ~~candidate~~ **candidates** . ~~To date, we have completed i) pre- clinical experiments in vitro and in vivo demonstrating potent tumor killing, ii) pilot toxicology studies, iii) received pre- IND feedback from the FDA, and iv) we are conducting ongoing activities associated with GLP toxicology studies, GMP manufacturing, and clinical development planning. We expect to file an IND by year- end 2024. 9Mechanism~~ - **Mechanism** of Action B7- H4 is a cell surface protein expressed on multiple tumor types and shows limited expression in most normal tissues. B7- H4 was initially discovered in 2003 in the Mayo Clinic lab of our scientific co- founder Dr. Lieping Chen. It is a member of the same family of co- inhibitory checkpoint proteins as B7- H1, known as PD- L1, which was also discovered by Dr. Chen' s laboratory. B7- H4 has been shown in published articles to negatively regulate T- cell immune response, inhibit cytokine production, suppress antigen- presenting cells, promote immune escape and play a role in tumorigenesis and tumor development. Expression of B7- H4 in tumor cells has been shown in preclinical research and published articles to be correlated with reduced overall survival, and B7- H4 has generally non- overlapping expression with PD- L1. LNCB74 is an anti- B7- H4 ADC that binds to B7- H4 on the cell surface and is internalized, upon which the linker is cleaved to release the MMAE payload, a well characterized microtubule- disrupting agent, and a commonly used payload in FDA approved ADCs. The mechanism of action of LNCB74 is shown in Figure 1 below: LNCB74 is comprised of a NextCure generated mAb intermediate, specific for B7- H4 protein, engineered with a sequence to facilitate site- specific conjugation of the antibody and linker arm to facilitate generation of an ADC. It is conjugated with a proprietary ~~LegoChem~~ **LigaChem** developed beta- glucuronide cleavable linker technology known as " ConjuAll " that leverages a novel selective payload release of MMAE for tumor killing and also allowing for " bystander " killing of neighboring tumor cells while minimizing toxicity in non- tumor cells. ~~Assets We Intend To PartnerBased~~ **7Clinical Development PlanWe initiated a Phase 1 dose- escalation and dose expansion / optimization study to evaluate the safety, tolerability and preliminary anti- tumor activity of LNCB74 in patients with tumor types known to have high B7- H4 expression. The dose escalation and backfill cohorts (Part 1) will identify two recommended dose levels for further evaluation based** on **safety and anti- tumor activity. Once the two recommended doses are established, tumor type- specific randomized dose expansion / optimization cohorts will be opened in Part 2 of the study. The objective of this part of the study will be to define a recommended Phase 2 dose and to define clinical activity in one** ~~our~~ - **or more histologically defined B7- H4 expressing tumor types for a potential single- arm or randomized registrational trial for accelerated approval. In February 2025, we cleared the first cohort in the dose escalation portion of the LNCB74 Phase 1 clinical trial and are currently within cohort 2. Based on our** ~~focused~~ - - **focus on LNCB74** ~~and prioritized pipeline~~ , we are seeking to partner, license ~~,~~ or advance through other strategic approaches **NC410 and** NC525 ~~and NC318~~ and our non- oncology preclinical programs **NC605 and NC181** . Clinical Oncology Programs **NC410 NC410 is a fusion protein of LAIR- 2, a naturally occurring soluble version of, and decoy protein for, LAIR- 1 that is designed to block immune suppression mediated by LAIR- 1. Early preclinical correlative biomarker work suggests that NC410 has the potential to overcome tumor resistance by remodeling the tumor' s extracellular matrix (ECM) to remove a physical barrier surrounding the tumor to enhance T cell tumor killing. We have exclusive worldwide rights to NC410.** NC525NC525 is a novel LAIR- 1 antibody that selectively targets Acute Myeloid Leukemia (AML), blast cells and leukemic stem cells (LSCs). Preclinical data show that NC525 kills AML blast cells and LSCs while sparing hematopoietic stem and progenitor cells (HSPCs). Preclinical data also show that NC525 **:** (i) inhibits colony formation of AML LSCs in vitro ~~,~~**;** (ii) inhibits AML growth in the MV4- 11 derived xenographs (CDX) animal model in vivo **;** and (iii) restricts AML progression in patient- derived xenografts (PDX) in vivo. We have exclusive worldwide rights to NC525. ~~10A Phase 1 trial was initiated in February 2023 to evaluate the safety and preliminary efficacy of NC525 in patients with AML, high- risk myelodyplastic syndrome, and chronic myelomonocytic leukemia (CMML). This open- label trial was designed to evaluate the safety and tolerability of NC525 and determine its pharmacologically active and / or maximum tolerated dose. We are currently in the fifth cohort of the dose escalation portion of the trial. Initial data suggest linear pharmacokinetics and an acceptable safety profile. We plan to complete the dose- finding portion of the study to arrive at a predicted biologically active dose. Based upon our decision to extend our cash runway and focus our resources on advancement of NC410 and LNCB74, we will further assess development plans for NC525 by the fourth quarter of 2024 in conjunction with our partnering efforts. NC318NC318 is a humanized IgG1 mAb against Siglec- 15 (S15), that blocks interactions of S15 with myeloid cells and T lymphocytes within the tumor microenvironment, relieving immune inhibitory signaling. In an earlier monotherapy study from NextCure, NC318 demonstrated single- agent activity in a Phase 1 / 2 dose escalation trial (NCT03665285) for patients with advanced solid tumors. We have exclusive worldwide rights to NC318. We are providing NC318 for an ongoing Phase 2 IIT with our founding institution, Yale University, to evaluate NC318 in combination with pembrolizumab in patients with non- small cell lung cancer (NSCLC). In September 2023, we announced the presentation of Phase 2 clinical~~ **Preclinical** ~~data by our collaborators at the Yale Cancer Center demonstrating clinical benefit in patients with advanced, PD- 1 axis inhibitor refractory non- small cell lung cancer (NSCLC) treated with a combination regimen of NC318, a S15 mAb, and pembrolizumab, an anti- PD- 1 antibody. Efficacy data demonstrate that the combination of NC318 and pembrolizumab is active in advanced PD- 1 axis inhibitor~~

~~refractory NSCLC: 28 % of patients (5 / 18) had durable clinical benefit (partial response or stable disease lasting greater than 6 months by RECIST and / or irRC) with 3 of these being confirmed responses. Yale is continuing to enroll patients to gain further evidence of clinical activity of NC318. Pre- Clinical Non- Oncology~~ Programs ~~In the second half of 2023, we announced two preclinical candidates that could be IND- ready in the first half of 2025 in the unmet needs areas of chronic bone diseases, including for an orphan indication for Osteogenesis Imperfecta (OI), and Alzheimer' s disease, a neurodegenerative disease. We will continue to seek global partners or other strategic approaches. We have leveraged our internal capabilities to advance these programs. NC605NC605 is an antibody that targets Siglec- 15. Preclinical data reported NC605 treatment reduced bone loss and enhanced bone quality in mice with OI. OI is a rare disorder that results in high bone turnover, abnormal bone formation, bone fragility, and recurrent fractures. NC605 could also have applications in chronic bone diseases such as osteoarthritis and non- union fractures. We are currently conducting toxicology studies.~~ NC181NC181 is a humanized antibody targeting ApoE4 for the treatment of Alzheimer' s disease (AD). In preclinical AD animal models, NC181 has demonstrated amyloid clearance, prevention of amyloid deposition, plaque clearance ~~,~~ and reduced neuroinflammation. Preclinical studies have demonstrated that NC181 reduces microhemorrhages and improves cerebral vascular function; lowers risk Amyloid Related Imaging Abnormalities (ARIA). ~~Alignment of Our Infrastructure~~ **We have exclusive worldwide rights** to **NC181. NC605NC605 is** ~~the Focused Pipeline In March 2024, we announced a prioritization and~~ **an** ~~restructuring of our operations to align~~ **antibody that targets Siglec- 15. Preclinical data reported NC605 treatment reduced bone loss and enhanced bone quality in mice** with ~~our focused pipeline approach~~ **OI. OI is a rare disorder that results in high bone turnover, abnormal bone formation, bone fragility, and recurrent fractures. NC605 could also have applications in chronic bone diseases such as osteoarthritis and non- union fractures. We have exclusive worldwide rights to NC605. We believe that both of these non- oncology programs have the potential to file** ~~and~~ **an** ~~extend our~~ **IND application within 12 to 18 months if** financial **support** ~~cash runway into the second half of 2026. We will focus our internal resources and retain our expertise in, clinical operations biomarker research, business development, and manufacturing tech transfer. As a result, we will pause our internal manufacturing operations because we believe ample clinical supply has been produced, including the LNCB74 mAb intermediate, to supply our prioritized programs in the near term. 11In conjunction with the restructuring, we are reducing our workforce~~ from **partners** ~~81 full- time employees to 51 employees. This reduction will primarily occur in our~~ **or third parties is secured** ~~manufacturing operations, but also will impact areas of discovery, research, development, clinical, and general administrative~~. ~~Our~~ **8Our** Collaboration ~~AgreementsLegoChem~~ **AgreementsLigaChem** AgreementIn November 2022, the Company entered into the ~~LegoChem~~ **LigaChem** Agreement to develop up to three ADCs. Under the terms of the ~~LegoChem~~ **LigaChem** Agreement, both parties equally share the costs of developing the ~~molecules~~ **ADC products** and profits on commercialized products. The collaboration consists of up to three research programs for which a research plan will be developed. With respect to a research plan, each party shall use reasonable efforts to execute and perform the activities assigned to it. Each party shall be solely responsible for costs associated with its assigned activities as outlined in the research plan. Upon successful completion of a research plan, or as otherwise agreed, the parties may designate a research product as a co- development product. Upon designation of a co- development product, **development of the product under a** cost sharing on a 50- 50 basis between the Company and ~~LegoChem~~ **LigaChem** would begin. The activities associated with the research plan and co- development products will be coordinated by a joint steering committee, which is comprised of an equal number of representatives from the Company and ~~LegoChem~~ **LigaChem** . If and when a co- development product becomes commercialized, the Company and ~~LegoChem~~ **LigaChem** would equally share in the profits. There are no implied licenses or other rights created under the ~~LegoChem~~ **LigaChem** Agreement after designation of a co- development product. Effective April 1, 2023, the parties designated LNCB74 as the first co- development product under the ~~LegoChem~~ **LigaChem** Agreement. As such, **LNCB74 is being advanced as the first co- development product under the LigaChem Agreement subject to** cost sharing on a 50- 50 basis **between Company and** ~~commenced for the first co- development product under the LegoChem~~ **LigaChem .** Agreement ~~. Agreements~~ with Yale ~~UniversityLicense~~ --- **UniversityWe** ~~Agreement with YaleWe~~ entered into a license agreement with Yale **University (" Yale ")** , ~~or~~ **in December 2015 (** the **"** Yale Agreement **")** ~~, in December 2015~~ pursuant to which we obtained an exclusive, royalty- bearing, sublicensable worldwide license to products that either incorporate certain licensed patents used in the discovery of targets or arise out of research and development of Dr. Chen' s laboratory at Yale, including S15 ~~, and~~ **. We** subsequently amended the Yale Agreement in January 2020 ~~and~~ **,** October 2021 **and September 2022** . We are obligated to pay Yale low single- digit royalties on sales of products that are either covered by the patents licensed to us under the Yale Agreement or arise out of work with Dr. Chen, including with his laboratory, as a result of research under the corporate sponsored research agreement described below, subject to minimum annual royalty payments in the low to mid hundreds of thousands of dollars. Until we are required to pay royalties under the Yale Agreement, we must pay an annual license maintenance fee to Yale in the mid to high tens of thousands of dollars. In addition, with respect to each product covered by licenses under the Yale Agreement, we are obligated to pay Yale milestone payments upon (i) the initiation of each of a Phase 1 clinical trial, Phase 2 clinical trial and Phase 3 clinical trial or a pivotal trial, (ii) first commercial sale in the United States and (iii) first commercial sale in China, Japan or a major European country, in an aggregate amount of up to $ 2, 975, 000. The term of the license agreement with Yale runs, on a country- by- country basis, until the later of the expiration of all licensed patents or 10 years from the first commercial sale in such country, unless Yale has cause to terminate earlier for our material breach of the license, bankruptcy or if we or any sublicensee bring a challenge against Yale in relation to the licensed patents. We have the right to terminate the Yale Agreement for Yale' s material breach or at any time during the term with six months' prior written notice to Yale ~~. Sponsored Research Agreement with YaleIn connection with the Yale Agreement, we also entered into a corporate sponsored research agreement, or " SRA ", with Yale, pursuant to which we had agreed to provide an aggregate of up to $ 15 million to fund a research program aimed at discovering new targets for therapies. The SRA was subsequently amended in January 2020, October 2021 and September 2022 and expired on March 31, 2023~~ . ManufacturingWe have a

purpose- built, dedicated, state- of- the- art cGMP manufacturing facility that utilizes single- use technology to support ~~our pipeline~~ and advance our product candidates into and through clinical development. The facility has a production capacity of 2, 000 liters that has supported our multiple product candidates. The investment in our ~~12manufacturing~~ -- **manufacturing** facility has been a critical element of our ability to quickly identify whether a candidate is likely to be successful and to facilitate an efficient development path. In March 2024, we paused our internal manufacturing operations **,** as we believe ample clinical supply has been produced, including the LNCB74 mAb intermediate, to supply programs in the near term. CompetitionThe biotechnology and pharmaceutical industries, and the oncology subsector, are characterized by rapid evolution of technologies, fierce competition and strong defense of intellectual property. We believe that our programs, platforms, technology, knowledge, experience and scientific resources provide us with competitive advantages, but we also face competition from pharmaceutical and biotechnology companies, academic institutions, governmental agencies and public and private research institutions, among others. Our competitors include larger and better funded biopharmaceutical, biotechnology and therapeutics companies, including companies focused on cancer immunotherapies. ~~Moreover~~ **9Moreover** , we may also compete with smaller or earlier- stage companies, universities and other research institutions that have developed, are developing or may be developing current and future cancer therapeutics. **LNCB74** ~~These competitors include: ● Development of immune- oncology treatments in combination with other commercial and investigational therapeutics. NC410~~ will compete with a range ~~of therapies that are currently approved and any new therapies that may become available in the future. Key product features that would affect our ability to effectively compete with other therapeutics include the efficacy, safety and convenience of our products. Currently marketed oncology drugs and therapeutics range from traditional cancer therapies, including chemotherapy, to antibody- drug conjugates, such as Genentech Inc.' s Kadcyla, to immune checkpoint inhibitors targeting CTLA- 4, such as BMS' Yervoy, and PD- 1 / PD- L1, such as BMS' Opdivo, Merck & Co.' s Keytruda and Genentech' s Tecentriq, to T- cell- engager immunotherapies, such as Amgen' s Blincyto. In addition to these marketed therapies, numerous compounds are in clinical development for the potential treatment of cancer. ● Development~~ of B7- H4 targeted programs ~~. LNCB74 will compete with a range of product candidates~~ currently in clinical trials ~~. These~~ **from companies** ~~include~~ **including Astra Zeneca plc** ~~ADC clinical programs being developed by Pfizer Inc.~~ ~~a~~ **BeiGene Ltd. (licensed from DualityBio),** GSK **plc (** licensed ~~candidate~~ from Hansoh Pharmaceutical Group Limited **)** , **and** Mersana ~~, and AstraZeneca plc, with~~ **. We are also aware of** additional B7- H4 ADCs in preclinical development **and** ~~. We are also aware of~~ other companies **'** development **of** ~~non- ADC approaches targeting~~ B7- H4 **targeting therapeutics that are not ADCs** . Our ability to compete effectively with other B7- H4 programs will depend on our ability to differentiate LNCB74 from **such** other therapies based on target tumor types, payload, efficacy and tolerability. Any inability to effectively differentiate LNCB74 from other product candidates targeting B7- H4 would negatively impact our ability to compete. ~~The availability of reimbursement from government and other third- party payors will also significantly affect the pricing and competitiveness of our products. Our competitors may also 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.~~ Intellectual PropertyOur commercial success depends in part on our ability to obtain and maintain proprietary protection for our products, methods and manufacturing processes, to operate without infringing on the proprietary rights of others and to prevent others from infringing on our proprietary rights. We rely on a combination of patents, patent applications and trade secrets, as well as contractual protections, to establish and protect our intellectual property rights. We seek to protect our proprietary position by, among other things, filing patent applications in the United States and internationally. Our patent estate includes patents and patent applications with claims relating to our product candidates, methods of use and manufacturing processes, and claims for potential future products and developments. As of December 31, ~~2023~~ **2024** , our intellectual property portfolio includes, on a worldwide basis, 20 pending foreign patent applications relating to NC318, NC410, NC525 and LNCB74, two pending U. S. patent application relating to NC318, one pending U. S. patent application relating to NC410, one pending U. S. patent application relating to LNCB74, one U. S. patent application relating to NC525 and additional pending patent applications for other discovery and research programs. Patents resulting from our patent applications for NC318, NC410 and NC525, if issued, are expected to expire beginning in 2037 absent any patent term adjustments or extensions and for LNCB74, if issued, are expected to expire beginning in 2045 absent any patent term adjustments or extensions. ~~13In~~ **In** addition, as described above, under the Yale Agreement, we have an exclusive, royalty- bearing, sublicensable worldwide license from Yale for an intellectual property portfolio, including among other things a patent relating to methods of use for S15 that covers the use of NC318 and a patent relating to our Functional, Integrated, NextCure Discovery (**"** FIND **"**) platform. These and any other patents that might issue from these licensed patent applications are expected to expire no earlier than 2036 absent any patent term adjustments or extensions. For all patent applications, we determine strategy for claim scope on a case- by- case basis, taking into account advice of counsel and our business model and needs. We file patents containing claims for protection of all useful applications of our proprietary technologies and any products, as well as all new applications and / or uses we discover for existing technologies and products, based on our assessment of their strategic value. We continuously reassess the number and type of patent applications, as well as the pending and issued patent claims to ensure that maximum coverage and value are obtained for our processes and compositions, given existing patent office rules and regulations. Further, claims may be modified during patent prosecution to meet our intellectual property and business needs. We also rely upon trade secrets, know- how and continuing technological innovation to develop and maintain our competitive position, including with respect to our FIND platform. We seek to protect our proprietary technology and processes, in part, by confidentiality and invention assignment agreements with our employees, consultants, scientific advisors and other contractors. In addition, in the ordinary course of our business, we enter into agreements with other third parties for non- exclusive rights to intellectual property directed to other technologies that are ancillary to our business, including laboratory information management software and research and development tools. In addition, we have trademark registrations with the U. S. Patent and Trademark Office, or the USPTO, for

“ NextCure ” and our logo. Government RegulationGovernment Regulation and Product ApprovalThe FDA and other regulatory authorities at federal, state and local levels, as well as in foreign countries, extensively regulate, among other things, the research, development, testing, manufacture, quality control, import, export, safety, effectiveness, labeling, packaging, storage, distribution, recordkeeping, approval, advertising, promotion, ~~marketing~~ **10marketing** , post- approval monitoring and post-approval reporting of biological products. Along with third- party contractors, we will be required to navigate the various preclinical, clinical and commercial approval requirements of the governing regulatory agencies of the countries in which we intend to conduct studies or seek approval or licensure of our product candidates. The processes for obtaining regulatory approvals in the United States and in foreign jurisdictions, along with subsequent compliance with applicable laws and regulations and other regulatory authorities, require the expenditure of substantial time and financial resources. Government policies may change, and additional government regulations may be enacted, that may prevent or delay further development or regulatory approval of any product candidates, product or manufacturing changes, additional disease indications or label changes. We cannot predict the likelihood, nature or extent of government regulation that might arise from future legislative or administrative action. Review and Approval for Licensing Biologics in the United StatesIn the United States, the FDA regulates our current product candidates as biological products, or biologics, under the Federal Food, Drug, and Cosmetic Act, or “ FDCA ”, the Public Health Service Act and associated implementing regulations. Biologics, like other drugs, are used for the treatment, prevention or cure of disease in humans. In contrast to small molecular weight drugs, which have a well- defined structure and can be thoroughly characterized, biologics are generally derived from living material (human, animal or microorganism) are complex in structure, and thus are usually not fully characterized. Biologics include therapies for cancer and other diseases. Biologics are also subject to other federal, state and local statutes and regulations. The failure to comply with applicable statutory and regulatory requirements at any time during the product development process, approval process or after approval may subject a sponsor or applicant to administrative or judicial enforcement actions. These actions could include the suspension or termination of clinical trials by the FDA, the FDA’ s refusal to approve pending applications or supplemental applications, withdrawal of an approval, Warning Letters or Untitled Letters, product recalls, product seizures, total or partial suspension of production or distribution, import detention, injunctions, fines, refusals of ~~14government~~ -- **government** contracts, restitution, disgorgement of profits, or civil or criminal investigations and penalties brought by the FDA, the Department of Justice, or the DOJ, or other governmental entities. An applicant seeking approval to market and distribute a biologic in the United States must typically undertake the following: ● completion of non- clinical laboratory tests and animal studies performed in accordance with the FDA’ s good laboratory practice, or “ GLP ”, regulations; ● manufacture, labeling and distribution of investigational drug in compliance with cGMP; ● submission to the FDA of an IND application, which must become effective before clinical trials may begin and must be updated annually or when significant changes are made; ● approval by an independent institutional review board, or “ IRB ”, or ethics committee at each clinical site before each clinical trial may be initiated; ● performance of adequate and well- controlled human clinical trials in accordance with the FDA’ s current Good Clinical Practices requirements, or “ cGCP ”, to establish the safety, purity and potency of the proposed biological product candidate for its intended purpose; ● preparation of and submission to the FDA of a biologics license application, or “ BLA ”, after completion of all pivotal clinical trials requesting marketing approval for one or more proposed indications; ● obtain satisfactory completion of an FDA Advisory Committee review, where appropriate, as may be requested by the FDA to assist with its review; ● satisfactory completion of one or more FDA inspections of the manufacturing facility or facilities at which the proposed product, or certain components thereof, are produced to assess compliance with cGMP and data ~~integrity~~ **11integrity** requirements to assure that the facilities, methods and controls are adequate to preserve the biologic’ s identity, safety, quality, purity and potency; ● satisfactory completion of FDA audits of selected clinical investigation sites to assure compliance with cGCP requirements and the integrity of the clinical data; ● payment of user fees under the Prescription Drug User Fee Act for the relevant year; ● obtain FDA review and approval of the BLA to permit commercial marketing of the licensed biologic for particular indications for use in the United States; and ● compliance with post- approval requirements, including the potential requirements to implement a Risk Evaluation and Mitigation Strategy, or “ REMS ”, adverse event and biological product deviation reporting and to complete any post- approval studies. From time to time, legislation is drafted, introduced and passed in Congress that could significantly change the statutory provisions governing the testing, approval, manufacturing and marketing of products regulated by the FDA. In addition to new legislation, FDA regulations and policies are often revised or interpreted by the agency in ways that may significantly affect our business and our products. It is impossible to predict whether further legislative changes will be enacted or whether FDA regulations, guidance, policies or interpretations will be changed or what the effect of such changes, if any, may be. Preclinical and Clinical DevelopmentBefore an applicant can begin testing the potential candidate in human subjects, the applicant must first conduct preclinical studies. Preclinical studies include laboratory evaluations of product chemistry, toxicity and formulation, as well as in vitro and animal studies to assess the potential safety and activity of the drug for initial testing in humans and to ~~15establish~~ -- **establish** a rationale for therapeutic use. Preclinical studies are subject to federal regulations and requirements, including GLP regulations. The results of an applicant’ s preclinical studies are submitted to the FDA as part of an IND. An IND is a request for authorization from the FDA to administer an investigational new drug product to humans. An IND is an exemption from the FDCA that allows an unapproved drug to be shipped in interstate commerce for use in an investigational clinical trial. Such authorization must be secured prior to interstate shipment and administration of a biologic that is not the subject of an approved BLA. In support of a request for an IND, applicants must submit a protocol for each clinical trial. Any subsequent protocol amendments must be submitted to the FDA as part of the IND. Human clinical trials cannot begin until an IND is effective. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA raises safety concerns or questions about the proposed clinical trial within the 30- day time period. In such a case, the IND may be placed on clinical hold and the IND sponsor and the FDA must resolve any outstanding concerns or questions before the clinical trial can begin. Submission of an IND therefore

may or may not result in FDA authorization to begin a clinical trial. The FDA may also place a clinical hold or partial clinical hold on such trial following commencement of a clinical trial under an IND. A clinical hold is an order issued by the FDA to the sponsor to delay a proposed clinical investigation or to suspend an ongoing investigation. A partial clinical hold is a delay or suspension of only part of the clinical work requested under the IND. For example, a specific protocol or part of a protocol is not allowed to proceed, while other protocols may do so. No more than 30 days after imposition of a clinical hold or partial clinical hold, the FDA will provide the sponsor a written explanation of the basis for the hold. Following issuance of a clinical hold or partial clinical hold, an investigation may only resume after the FDA has notified the sponsor that the investigation may proceed. The FDA will base that determination on information provided by the sponsor correcting the deficiencies previously cited or otherwise satisfying the FDA that the investigation can proceed. Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with cGCP regulations, which include the requirement that all research subjects provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the trial, the parameters to be used in monitoring safety and the ~~effectiveness~~ **12effectiveness** criteria to be evaluated. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development and for any subsequent protocol amendments. A sponsor may choose, but is not required, to conduct a foreign clinical study under an IND. When a foreign clinical study is conducted under an IND, all FDA IND requirements must be met unless waived. When the foreign clinical study is not conducted under an IND, the sponsor must ensure that the study complies with cGCP regulations in order to use the study as support for an IND or application for marketing approval, including cGCP regulations, including review and approval by an independent ethics committee and informed consent from subjects. Furthermore, an independent IRB for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial and its informed consent form before the clinical trial begins at that site and must monitor the trial until completed. Regulatory authorities, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk or that the trial is unlikely to meet its stated objectives. Some trials also include oversight by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board, or " DSMB ". DSMBs provide recommendations for whether or not a trial may move forward at designated check points based on access to certain data from the trial and may recommend halting the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy. Other grounds for suspension or termination may be made based on evolving business objectives and / or competitive climate. There are also requirements governing the reporting of ongoing clinical trials and clinical trial results to public registries. ~~16Clinical~~ -- **Clinical** TrialsFor purposes of BLA approval, clinical trials are typically conducted in the following sequential phases: ● Phase 1: The investigational product is initially introduced into healthy human subjects or patients with the target disease or condition. These trials are designed to test the safety, dosage tolerance, absorption, metabolism and distribution of the investigational product in humans and the side effects associated with increasing doses. These trials may also yield early evidence of effectiveness. ● Phase 2: The investigational product is administered to a limited patient population with a specified disease or condition to evaluate the preliminary efficacy, optimal dosages and dosing schedule and to identify possible adverse side effects and safety risks. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials. ● Phase 3: The investigational product is administered to an expanded patient population to further evaluate dosage, to provide statistically significant evidence of clinical efficacy and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to generate sufficient data to statistically evaluate the efficacy and safety of the product for approval, to establish the overall risk / benefit ratio of the investigational product and to provide an adequate basis for product approval by the FDA. These phases may overlap or be combined. In some cases, the FDA may require, or companies may voluntarily pursue, additional clinical trials, after a product is approved, to gain more information about the product, referred to as Phase 4 trials. Such post- approval trials, when applicable, are conducted following initial approval, typically to develop additional data and information relating to the biological characteristics of the product and treatment of patients in the intended therapeutic indication. Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and more frequently if serious adverse events occur. In addition, IND safety reports must be submitted to the FDA for any of the following: suspected serious and unexpected adverse reactions; findings from epidemiological studies, pooled analysis of multiple studies, animal or in vitro testing, or other clinical studies, whether or not conducted under an IND, and whether or not conducted by the sponsor, that suggest a significant risk in humans exposed to the drug; and any clinically important increase in the rate of a serious suspected adverse reaction over such rate listed in the protocol or investigator brochure. ~~Our~~ **13Our** ongoing and planned clinical trials may not be completed successfully within any specified period, or at all. Furthermore, the FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution, or an institution it represents, if the clinical trial is not being conducted in accordance with the IRB' s requirements or if the drug has been associated with unexpected serious harm to patients. The FDA will typically inspect one or more clinical sites to assure compliance with cGCP and the integrity of the clinical data submitted. During clinical development, the sponsor often refines the indication and endpoints on which the BLA will be based. For endpoints based on patient- reported outcomes, or " PROs ", and ~~outcome~~ **observer** reported outcomes, or " OROs ", the process typically is an iterative one. The FDA has issued guidance on the framework it uses to evaluate PRO instruments. Although the agency may offer advice on optimizing PRO and ORO instruments during the clinical development process, the FDA usually reserves final judgment until it reviews the BLA. Concurrent with clinical trials, companies often complete additional animal studies, and develop additional information about the chemistry and physical characteristics of the drug and finalize a process for manufacturing the product in commercial quantities in accordance with cGMP. The manufacturing process must be capable

of consistently producing quality batches of the drug candidate and, among other things, must develop methods for testing the identity, strength, quality, purity and potency of the final drug. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the drug candidate does not undergo unacceptable deterioration over its shelf life. ~~17BLA --~~ **BLA** Submission and ReviewIf an applicant successfully completes all required clinical testing in accordance with all applicable regulatory requirements, an applicant may submit a BLA requesting licensing to market the biologic for one or more indications in the United States. The BLA must include the results of product development, nonclinical studies and clinical trials; detailed information on the product' s chemistry, manufacture, controls and proposed labeling. Under the Prescription Drug User Fee Amendments, a BLA submission is subject to an application user fee, unless a waiver or exemption applies. The cost of preparing and submitting a BLA is substantial. These fees are typically increased annually. The FDA will initially review the BLA for completeness before accepting it for filing. Under the FDA' s procedures, the agency has 60 days from its receipt of a BLA to determine whether the application will be accepted for filing and substantive review. If the agency determines that the application does not meet this initial threshold standard, the FDA may refuse to file the application and request additional information, in which case the application must be resubmitted with the requested information and review of the application delayed. With certain exceptions, BLAs must include a pediatric assessment, generally based on clinical trial data, of the safety and effectiveness of the biologic in relevant pediatric populations. Under certain circumstances, the FDA may waive or defer the requirement for a pediatric assessment, either at the sponsor' s request or by the agency' s initiative. After the BLA is accepted for filing, the FDA reviews the BLA to determine, among other things, whether a product is safe, pure and potent and if the facility in which it is manufactured, processed, packed or held meets standards designed to assure the product' s continued identity, strength, quality, safety, purity and potency. The FDA may convene an advisory committee to provide clinical insight on application review questions. Before approving a BLA, the FDA will typically inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities comply with cGMP and are adequate to assure consistent production of the product within required specifications. In addition, the FDA expects that all data be reliable and accurate and requires sponsors to implement meaningful and effective strategies to manage data integrity risks. Data integrity is an important component of the sponsor' s responsibility to ensure the safety, efficacy and quality of its product or products. The FDA will typically inspect one or more clinical sites to assure compliance with cGCP regulations before approving a BLA. If the FDA determines that the application, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. ~~FDA~~ **14FDA** performance goals generally provide for action on a BLA within 10 months of filing, which (as discussed above) typically occurs within 60 days of submission, but that deadline is extended in certain circumstances. Furthermore, the review process is often significantly extended by the FDA' s requests for additional information or clarification. The FDA may refer applications for novel products or products that present difficult questions of safety or efficacy to an advisory committee. Typically, an advisory committee consists of a panel that includes clinicians and other experts who will review, evaluate and provide a recommendation as to whether the application should be approved and, if so, under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions and usually has followed such recommendations. After the FDA evaluates a BLA and conducts inspections of manufacturing facilities where the investigational product and / or its components will be produced, the FDA may issue an approval letter or a Complete Response Letter, or " CRL ". An approval letter authorizes commercial marketing of the biologic with specific prescribing information for specific indications. A CRL will describe all of the deficiencies that the FDA has identified in the BLA, except that where the FDA determines that the data supporting the application are inadequate to support approval, the FDA may issue the CRL without first conducting required inspections, testing submitted product lots and / or reviewing proposed labeling. If the deficiencies have been addressed to the FDA' s satisfaction in a resubmission of the BLA, the FDA will issue an approval letter. In issuing the CRL, the FDA may recommend actions that the applicant might take to place the BLA in condition for approval, including requests for additional data, information or clarification. The FDA may delay or refuse approval of a BLA if applicable regulatory criteria are not satisfied and may require additional testing or information ~~18and --~~ **and** / or require post-marketing studies and clinical trials. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. During the approval process, the FDA will determine whether a REMS is necessary to assure the safe use of the biologic. A REMS is a safety strategy to manage a known or potential serious risk associated with a product and to enable patients to have continued access to such medicines by managing their safe use, and could include medication guides, physician communication plans or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. If the FDA concludes that a REMS is needed, the BLA sponsor must submit a proposed REMS and the FDA will not approve the BLA without a REMS that the agency has determined is acceptable. If the FDA approves a product, it may limit the approved indications for use for the product, or require that contraindications, warnings or precautions be included in the product labeling. The FDA may also require that post- approval studies, including Phase 4 clinical trials, be conducted to further assess the drug' s safety after approval. The FDA may prevent or limit further marketing of a product based on the results of post- market studies or surveillance programs. The FDA may also require testing and surveillance programs to monitor the product after commercialization. For biologics, such testing may include official lot release, which requires the manufacturer to perform certain tests on each lot of the product before it is released for distribution. The manufacturer then typically must submit samples of each lot of product to the FDA, together with a release protocol showing a summary of the history of manufacture of the lot and the results of all of the manufacturer' s tests performed on the lot. The FDA may also perform certain confirmatory tests on lots of some products itself, before releasing the lots for distribution by the manufacturer. After approval, many types of

changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are often subject to further testing requirements and FDA review and approval, depending on the nature of the post- approval change. The FDA may withdraw the product approval if compliance with pre- and post- marketing requirements is not maintained or if problems occur after the product reaches the marketplace. Post- Approval RequirementsAny products manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, reporting of certain deviations and adverse experiences, product sampling and distribution and advertising and promotion of the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to FDA review and approval. Biologic manufacturers and their third- party contractors are required to register their facilities with the FDA and certain state agencies. These facilities are subject to routine and periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP, post- marketing safety reporting and data integrity requirements, which impose certain procedural and documentation requirements to assure quality of ~~manufacturing~~ **15manufacturing** and product. FDA has increasingly observed cGMP violations involving data integrity during site inspections and is a significant focus of its oversight. Requirements with respect to data integrity include, among other things, controls to ensure data are complete and secure; activities documented at the time of performance; audit trail functionality; authorized access and limitations; validated computer systems; and review of records for accuracy, completeness and compliance with established standards. Post- approval changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting requirements upon us and any third- party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP, data integrity, pharmacovigilance and other aspects of regulatory compliance. ~~19The~~ -- **The** FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post- approval studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS. Other potential consequences include, among other things: ● restrictions on the marketing or manufacturing of a product, complete withdrawal of the product from the market or product recalls; ● fines, Warning Letters, Untitled Letters or holds on post- approval clinical studies; ● refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of existing product approvals; ● product seizure or detention, or refusal of the FDA to permit the import or export of products or Import Alert; or ● permanent injunctions and consent decrees, including the imposition of civil or criminal penalties. The FDA strictly regulates the marketing, labeling, advertising and promotion of prescription drug and biological products placed on the market. A company can make only those claims relating to safety and efficacy, purity and potency that are approved by the FDA and in accordance with the provisions of the approved label. The FDA' s regulation includes, among other things, standards and regulations for direct- to- consumer advertising, communications regarding unapproved uses, industry- sponsored scientific and educational activities and promotional activities involving the Internet and social media. Promotional claims relating to a product' s safety or effectiveness are prohibited before the drug is approved. After approval, a product generally may not be promoted for uses that are not approved by the FDA, as reflected in the product' s prescribing information. In the United States, healthcare professionals are generally permitted to prescribe drugs for such uses not described in the drug' s labeling, known as off- label uses, because the FDA does not regulate the practice of medicine. However, FDA regulations impose rigorous restrictions on manufacturers' communications, prohibiting the promotion of off- label uses. It may be permissible, under very specific, narrow conditions, for a manufacturer to engage in non- promotional, non- misleading communication regarding off- label information, such as distributing scientific or medical journal information. If a company is found to have promoted off- label uses, it may become subject to adverse public relations and administrative and judicial enforcement by the FDA, the DOJ or the Office of the Inspector General of the Department of Health and Human Services, or " HHS ", as well as other federal and state authorities. This could subject a company to a range of penalties that could have a significant commercial impact, including civil, administrative, and criminal fines, penalties, and agreements that materially restrict the manner in which a company promotes or distributes products. The federal government has levied large civil, administrative, and criminal fines and penalties against companies for alleged improper promotion and has also requested that companies enter into consent decrees and permanent injunctions under which specified promotional conduct is changed or curtailed. ~~The~~ **16The** distribution of prescription drug and biological products are subject to the Drug Supply Chain Security Act, or " DSCSA ", which requires manufacturers and other stakeholders to comply with product identification, tracing, verification, detection and response, notification and licensing requirements. In addition, the Prescription Drug Marketing Act and its implementing regulations and state laws limit the distribution of prescription pharmaceutical product samples, and the DSCSA imposes requirements to ensure accountability in distribution and to identify and remove prescription drug and biological products that may be counterfeit, stolen, contaminated, or otherwise harmful from the market. Patent Term Restoration After approval, owners of relevant drug or biological product patents may apply for up to a five- year patent extension to restore a portion of patent term lost during product development and FDA review of a BLA under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch- Waxman Act. The allowable patent term extension is calculated as one- half of the product' s testing phase, which is the time between IND and BLA submission, and all of the review phase, which is the time between BLA submission and approval, up to a maximum of ~~20five~~ -- **five** years. The time can be shortened if the FDA determines that the applicant did not pursue approval with due diligence. The total patent term after the extension may not exceed more than 14 years from the date of FDA approval of the product. Only one patent claiming each approved product is eligible for restoration and the patent holder must apply for

restoration within 60 days of approval. The USPTO, in consultation with the FDA, reviews and approves the application for patent term restoration. For patents that might expire during the application phase, the patent owner may request an interim patent extension. An interim patent extension increases the patent term by one year and may be renewed up to four times. For each interim patent extension granted, the post- approval patent extension is reduced by one year. The director of the USPTO must determine that approval of the product candidate covered by the patent for which a patent extension is being sought is likely. Interim patent extensions are not available for a product candidate for which a BLA has not been submitted. Biosimilars and Marketing ExclusivitiesThe Biologics Price Competition and Innovation Act, or " BPCIA, " created an abbreviated approval pathway for biological product candidates shown to be highly similar to or interchangeable with an FDA licensed biological product. A biological product on which another biological product candidate' s BLA relies to establish biosimilarity is known as a reference product. Biosimilarity sufficient to reference a prior FDA- approved product requires that the biological product candidate be highly similar to the reference product not withstanding minor differences in clinically inactive components, and there be no clinically meaningful differences between the biological product candidate and the reference product in terms of safety, purity and potency. Biosimilarity must be shown through analytical trials, animal trials and at least one clinical trial, unless the FDA waives a required element. A biosimilar product candidate may be deemed interchangeable with a prior approved product if it meets the higher hurdle of demonstrating that it can be expected to produce the same clinical results as the reference product and, for products administered multiple times, the biologic and the reference biologic may be switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. Complexities associated with the larger, and often more complex, structures of biologics, as well as the process by which such products are manufactured, pose significant hurdles to implementation of the abbreviated approval pathway that are still being worked out by the FDA. A reference biologic is granted 12 years of exclusivity from the time of first licensure of the reference product, and no application for a biosimilar can be submitted for four years from the date of licensure of the reference product. The first interchangeable biosimilar biological product has exclusivity against a finding of interchangeability for other biologics for the lesser of (i) one year after first commercial marketing of the first interchangeable biosimilar, (ii) 18 months after the first interchangeable biosimilar is approved if there is no patent challenge, (iii) 18 months after resolution of a lawsuit over the patents of the reference biologic in favor of the first interchangeable biosimilar applicant, or (iv) 42 months after the first interchangeable biosimilar' s application has been approved if a patent lawsuit is ongoing within the 42 month period. State pharmacy laws and regulations govern whether products deemed " interchangeable " by the FDA will, in fact, be readily substituted by pharmacies, and may impose additional requirements such as notification of prescriber and / or patient, documentation and recordkeeping. If a biologic is designated and approved for an orphan indication, it will be granted seven years of orphan drug exclusivity. An orphan indication is granted to biological products and drugs designated and approved to treat diseases or ~~conditions~~ **17conditions** affecting fewer than 200, 000 individuals in the United States, or if there is no reasonable expectation that the sponsor will be able to recover the costs of developing and marketing the drug or biological product in the United States. During the seven- year exclusivity period, the FDA may not approve any other applications to market the same drug or biological product for the same disease, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity. A biosimilar may not be licensed by FDA for the protected orphan indication until after the expiration of the seven- year orphan drug exclusivity period or the 12- year reference product exclusivity, whichever is later. Pediatric exclusivity adds an additional six- month exclusivity period to any marketing exclusivities and patents that a biological product has obtained. In order to obtain pediatric exclusivity, a BLA sponsor must conduct pediatric studies as requested by the FDA in a Written Request. The data do not need to show the product to be effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA' s request, the additional protection is granted. If reports of requested pediatric studies are submitted to and accepted by the FDA within the statutory time limits, whatever statutory or regulatory periods of exclusivity or patent protection cover the product are extended by ~~21six~~ -- **six** months. While pediatric exclusivity is not an actual extension on a patent term, it effectively extends the preclusive effect of the patent on FDA' s authority to approve another application that relies on the product with pediatric exclusivity. The BPCIA is complex and continues to be interpreted and implemented by the FDA. On December 20, 2019, President Trump signed into law H. R. 1865, the Further Consolidated Appropriations Act of 2020. The law includes significant provisions concerning the FDA' s implementation of the BPCIA, such as clarifying that " chemically synthesized polypeptides " are no longer excluded from being regulated as biologics, while " peptides " (polymers composed of 40 or fewer amino acids) will continue to be regulated as drugs unless they otherwise meet the statutory definition of biological products. In addition, the Further Consolidated Appropriations Act of 2020 clarifies exclusivity and procedural issues related to certain biologics approved as drugs pursuant to new drug applications, or " NDAs ", to be the subject of an approved BLA, or transition biological products. The law also incorporates provisions intended to reduce price and increase competitiveness in the pharmaceutical industry. The law amends the FDCA to create a private right of action against NDA or BLA holders that refuse to provide sufficient quantities of samples of an approved reference product to generic and biosimilar developers. In July 2018, the FDA released its Biosimilars Action Plan to improve the efficiency of the biosimilar and interchangeable product development and approval process. The Further Consolidated Appropriations Act of 2020 is consistent with FDA guidance documents issued in December 2018 that were intended to advance the agency' s biosimilars policy framework. The implementation of the Further Consolidated Appropriations Act of 2020 and the ultimate impact of the agency' s Biosimilars Action Plan are uncertain and may evolve over time through future laws and regulations and guidance provided by regulatory and governing bodies. In addition, there has been discussion of whether Congress should reduce the 12- year reference product exclusivity period. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have been the subject of recent litigation. As a result, the ultimate implementation of the BPCIA is subject to significant uncertainty. Regulation of Companion Diagnostics and Laboratory Developed TestsA companion diagnostic is an in vitro diagnostic that can: identify the patients most

likely to benefit from a particular therapeutic product; identify those likely to be at an increased risk for serious side effects; or monitor responses to treatment with a particular therapeutic product for the purpose of adjusting treatment to achieve improved safety or effectiveness. Under the FDCA, in vitro companion diagnostics are generally regulated as medical devices. The FDA has generally classified in vitro companion diagnostics as high- risk, Class III devices, which require FDA approval of a premarket approval application, or " PMA ", but recognizes the possibility of a moderate- risk IVD companion diagnostic (i. e., Class II device), which would require clearance of a 510 (k) premarket notification or grant of a de novo request. Approval or clearance of the in vitro companion diagnostic device will ensure that the device has been adequately evaluated and has adequate performance characteristics in the intended population. For those in vitro companion diagnostics that require PMA approval, the process involves gathering and submitting clinical and preclinical data on the device for review by the FDA. It involves a rigorous premarket review, during which the applicant must provide the FDA with reasonable assurance of the device' s safety and effectiveness, as well as information regarding the device' s design, manufacturing and labeling. In addition, the FDA will typically inspect the device manufacturer' s facilities for compliance with the Quality System Regulation, which imposes testing, control, documentation and other quality assurance requirements. ~~The~~ **18The** FDA has issued guidance on the approval of therapeutic products and in vitro companion diagnostic devices. According to the FDA' s guidance, for novel therapeutic products including biologics, an in vitro companion diagnostic device and its corresponding therapeutic should be approved or cleared contemporaneously by the FDA for the use indicated in the therapeutic product' s labeling. In some cases, information from a diagnostic test may be useful to a prescriber, but not necessary for the safe and effective administration of the therapeutic product. In those cases, health care providers may employ information derived from a complementary diagnostic test such as a laboratory developed test, or " LDT ", when administering a therapeutic product. An LDT is a type of in vitro diagnostic test that is designed, manufactured and used within a single laboratory. LDTs can be used to measure or detect a wide variety of analytes (substances such as proteins, chemical compounds like glucose or cholesterol, or DNA), in a sample taken from a human body. The Centers for Medicare and Medicaid Services, or " CMS ", regulates LDTs and the laboratories that develop them, and enforces the Clinical Laboratories Improvement Amendments, or " CLIA ". CMS evaluates whether there is clinical utility for each specific test, and also performs post- market oversight of laboratory operational processes. CMS' s ~~22oversight~~ -- **oversight** through the CLIA program is designed to confirm that a lab assesses analytical validity but does not confirm whether it had results from an analytical validity assessment that were sufficient to support the claimed intended use of the test. Historically, the FDA has generally not enforced premarket review and other FDA requirements on LDTs because LDTs were relatively simple lab tests and generally available on a limited basis. Due to advances in technology, however, some LDTs are now much more complex, have a nationwide reach and present higher risks, such as detection of risk for breast cancer and Alzheimer' s disease, which are similar to those of other IV in vitro diagnostics that have undergone premarket review. In **May** ~~2023~~ **2024** , **the** FDA ~~announced~~ **finalized** a ~~proposed~~ rule **asserting** that ~~would explicitly assert that~~ **LDTs are medical devices subject to the requirements applicable to other** in vitro diagnostic **, or " IVD ",** products ~~(IVDs) are~~ **, and the FDA plans to phase in the enforcement of medical** ~~devices~~ - **device requirements to LDTs over** ~~under the FDCA, including when the manufacturer of the IVD is~~ a ~~laboratory~~ **period of four years** . ~~Along~~ **In connection** with ~~this amendment~~ **the final rule** , the FDA **established certain new, targeted** ~~proposed a policy under which the FDA would provide greater oversight of LDTs through a phaseout of its general~~ enforcement discretion ~~approach~~ **policies, including, among others,** for ~~most~~ LDTs ~~. Future language in~~ **marketed as of the date of publication of** the final rule ~~may further alter~~ **(May 6, 2024), as well as for LDTs that have received approval from New York State' s Clinical Laboratory Evaluation Program (" NY CLEP "). Specifically,** the **FDA intends to exercise enforcement discretion and not enforce certain medical device requirements, including the requirements for marketing authorization and compliance with certain elements of the Quality System** ~~regulation~~ **Regulation (" QSR "), with respect to LDTs that were marketed as** of ~~IVDs~~ **the date of the final rule' s publication, although such products must still comply with certain other FDA requirements, including registration and listing, portions of the QSR, medical device reporting, labeling, and corrections and removals reporting. However, where these tests are modified in certain ways from the version of the test marketed as of the final rule' s publication date, this enforcement discretion policy will no longer apply, and the FDA intends to enforce all applicable FDA requirements (including premarket review and marketing authorization requirements) consistent with the phase- in policy. In addition, for LDTs that receive approval from NY CLEP, the FDA intends not to enforce marketing authorization requirements when these requirements are phased in more generally at either three and a half or four years following the date of publication of the final rule. However, these tests will still be subject to the remaining medical device requirements, including registration and listing, medical device reporting, and quality system requirements, at the time that such requirements are phased in more generally. The final rule is currently subject to legal challenge before a court in the Eastern District of Texas. In addition, Congress has for over the past decade, considered a number of proposals, which, if enacted, would subject LDTs to additional or different regulatory requirements. Depending on the approach adopted under any potential legislation, certain LDTs (likely those of higher risk) may be required to undergo some form of premarket review, potentially with a transition period for compliance and a grandfathering provision** . New laws, regulations or changes to existing laws, regulations and policies may result in changes to the requirements for LDTs or in vitro diagnostic devices and to the FDA' s compliance and enforcement policies. ~~Healthcare~~ **19Healthcare** RegulationPharmaceutical Coverage and ReimbursementOur ability to successfully commercialize any of our product candidates for which we may receive regulatory approval will depend in significant part on the availability of coverage and reimbursement from third- party payors, including governmental healthcare programs, such as the Medicare and Medicaid programs in the U. S., private health insurers, managed care organizations, and other entities. Third- party payors may limit coverage to specific products on an approved list, or formulary, which might not include one or more of our product candidates. Third- party payors, together with regulators and others, are increasingly challenging the prices charged for pharmaceutical products and related services, in addition to their cost-

effectiveness, safety and efficacy. No uniform policy for coverage and reimbursement exists in the United States. Though we expect our initial product offering to be covered under Medicare Part B, and third- party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies, payors have their own methods and approval processes apart from Medicare determinations. Therefore, the availability and scope of coverage, as well as reimbursement rates can vary significantly from payor to payor. The marketability of any products for which we may receive regulatory approval for commercial sale depends on these payors' coverage policies and reimbursement rates. Moreover, obtaining coverage and adequate reimbursement is a time- consuming and costly process. We may be required to provide scientific and clinical support for the use of any product to each third- party payor separately with no assurance that approval will be obtained, and we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the cost-effectiveness of our products. We cannot be certain that our product candidates will be considered cost- effective by third- party payors. This process could delay the market acceptance of any product candidates for which we may receive approval and could have a negative effect on our future revenues and operating results. Other U. S. Healthcare Laws and Compliance RequirementsIn the United States, our business is subject to healthcare fraud and abuse regulation and enforcement by both the federal government and the states in which we conduct our business, particularly once third- party reimbursement becomes available for one or more of our products. The healthcare fraud and abuse laws and regulations that may affect our ability to operate include but are not limited to: ● The federal Anti- Kickback Statute is a criminal law that prohibits any person or entity from, among other things, knowingly and willfully soliciting, receiving, offering, providing, or paying any remuneration (including any kickback or bribe), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order, arranging for or recommending the purchase, lease, or order of any item or service for which payment may be made, in whole or in part, under federal healthcare programs, ~~like~~ **such as** Medicare or Medicaid. A person or entity can be found guilty of ~~23violating~~ -- **violating** the statute without actual knowledge of the statute or specific intent to violate it. The federal Anti- Kickback Statute has been interpreted to apply, for example, to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers, and formulary managers on the other, including, for example, consulting / speaking arrangements, discount and rebate offers, grants, charitable contributions, and patient support offerings, among others. A conviction for violation of the federal Anti- Kickback Statute can result in criminal fines and / or imprisonment and requires mandatory exclusion from participation in federal health care programs. Exclusion may also be imposed if the government determines that an entity has committed acts that are prohibited by the federal Anti- Kickback Statute. Although there are a number of statutory exceptions and regulatory safe harbors to the federal Anti- Kickback Statute protecting certain common business arrangements and activities from prosecution or regulatory sanctions, the exceptions and safe harbors are drawn narrowly. Practices that involve remuneration to those who prescribe, purchase, or recommend pharmaceutical and biological products that are not designed to fit squarely within an exception or safe harbor are evaluated based on the specific facts and circumstances and are typically subject to increased scrutiny. Our practices may not in all cases meet all of the criteria for safe harbor protection from Anti- Kickback Statute liability. ● The federal civil and criminal false claims laws and civil monetary penalty laws, including the civil False Claims Act, or " FCA ", which prohibits anyone from, among other things: (i) knowingly presenting, or causing to be presented, claims for payment of government funds that are false or fraudulent; (ii) knowingly ~~making~~ **20making** , or using or causing to be made or used, a false record or statement material to a false or fraudulent claim; (iii) knowingly making, using or causing to made or used a false record or statement material to an obligation to pay money to the government; or (iv) knowingly concealing or knowingly and improperly avoiding, decreasing, or concealing an obligation to pay money to the federal government. Private individuals, commonly known as " whistleblowers, " can bring FCA qui tam actions, on behalf of the government and may share in amounts paid by the defendant to the government in recovery or settlement. Pharmaceutical companies have been investigated and / or subject to government enforcement actions asserting liability under the FCA in connection with their alleged off- label promotion of drugs, purportedly concealing price concessions in the pricing information submitted to the government for government price reporting purposes, and allegedly providing free product to customers with the expectation that the customers would bill federal healthcare programs for the product, among other things. In addition, a claim including items or services resulting from a violation of the federal Anti- Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA. Moreover, manufacturers can be held liable under the FCA even though they, in most cases, do not submit claims directly to government payors if they are deemed to " cause " the submission of false or fraudulent claims. FCA liability is potentially significant in the healthcare industry because the statute provides for treble damages and significant mandatory penalties per false or fraudulent claim or statement for violations. Such per- claim penalties are currently set at $ ~~13~~ **14** , ~~946~~ **083** to $ ~~27~~ **28** , ~~894~~ **619** per false claim for penalties assessed after January 15, ~~2024~~ **2025** with respect to violations occurring after November 2, 2015. Criminal penalties, including imprisonment and criminal fines, are also possible for making or presenting a false, fictitious or fraudulent claim to the federal government; ● The federal Health Insurance Portability and Accountability Act of 1996, or " HIPAA ", which, among other things, prohibits knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third- party payors, and prohibits (i) knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement or representation and (ii) making or using any false writing or document knowing the same to contain any materially false, fictitious or fraudulent statement or entry in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity can be found guilty of violating the HIPAA fraud provisions without actual knowledge of the statute or specific intent to violate it; ● HIPAA, the Health Information Technology for Economic and Clinical Health Act, or " HITECH Act ", and HIPPAA' s implementing regulations, and certain state and local laws impose requirements relating to the privacy, security and transmission of individually identifiable health information held by covered entities, including health plans, healthcare clearinghouses and certain healthcare providers, and their business associates, individuals or entities that

perform certain services on behalf of a covered entity that involve the use or disclosure of individually identifiable health information. HIPAA includes several tiers of civil monetary penalties as well as criminal penalties. In addition, state attorneys general have authority to file ~~24civil --~~ **civil** actions for damages or injunctions in federal courts to enforce HIPAA and seek attorneys' fees and costs associated with pursuing federal civil actions. Research institutions that we collaborate with and healthcare providers who may prescribe our products, once commercialized, are subject to privacy and security requirements under HIPAA. The Department of Health and Human Services Office for Civil Rights (OCR) has recently increased its enforcement efforts on compliance with HIPAA, including the security regulations (Security Rule), bringing actions against entities which have failed to implement security measures sufficient to reduce risks to electronic protected health information or to conduct an accurate and thorough risk analysis, among other violations. Although we are not directly subject to HIPAA other than with respect to providing certain employee benefits, we could potentially be subject to criminal penalties if we, our affiliates or our agents knowingly obtain or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA; ● Numerous other federal and state laws and regulations that also govern the privacy and security of individually identifiable health information, including state data breach notification laws, state health information or genetic privacy laws, and federal and state consumer protection laws such as Section 5 of the Federal Trade Commission, or " FTC ", Act and the California Consumer Privacy Act, or " CCPA ". The CCPA gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing and receive detailed information about how their personal information is used by requiring covered companies to provide new disclosures to California consumers (as that term is broadly ~~defined~~ **21defined**) and provide such consumers new ways to opt- out of certain sales of personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. Although there are certain exemptions for personal information subject to HIPAA and personal data collected in a clinical trial context, the CCPA' s implementation standards and enforcement practices may increase our compliance costs and potential liability. Additionally, a California ballot initiative, the California Privacy Rights Act, or " CPRA ", passed in November 2020, and went into effect on January 1, 2023. The CPRA will impose additional data protection obligations on companies doing business in California, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. It also created a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. Additional compliance investment and potential business process changes may be required. Laws similar to the California laws have passed in states such as Virginia and Colorado, and comparable laws have been proposed in other states and at the federal level that may ultimately have conflicting requirements that would further complicate compliance and adversely affect our business. ● The FTC and many state attorneys general are interpreting existing federal and state consumer protection laws to impose evolving standards for the collection, use, dissemination and security of health- related and other personal information. For instance, the FTC has promulgated standards for fair information practices, which concern consumer notice, choice, security and access, and also require notice of certain health information breaches outside the HIPAA context. Consumer protection laws require us to publish statements that describe how we handle personal information and choices individuals may have about the way we handle their personal information. Violating consumers' privacy rights, publishing untrue information about security practices, or failing to take appropriate steps to keep consumers' personal information secure may constitute unfair or deceptive acts or practices in violation of Section 5 of the FTC Act. Additionally, the FTC recently published an advance notice of proposed rulemaking on commercial surveillance and data security and is seeking comment on whether it should implement new trade regulation rules or other regulatory alternatives concerning the ways in which companies (1) collect, aggregate, protect, use, analyze, and retain consumer data, as well as (2) transfer, share, sell, or otherwise monetize that data in ways that are unfair or deceptive. Federal regulators, state attorneys general and plaintiffs' attorneys have been and will likely continue to be active in this space, and if we do not comply with existing or new laws and regulations related to patient health information, we could be subject to criminal or civil sanctions. ● In addition, some countries are considering or have passed legislation implementing data protection requirements or requiring local storage and processing of data or similar requirements that could increase the cost and complexity of research activities. These laws and regulations, as well as any associated claims, inquiries, investigations or any other government actions may lead to unfavorable outcomes including increased compliance costs, delays or impediments in the development of new products, negative publicity, ~~25increased --~~ **increased** operating costs, diversion of management time and attention and remedies that harm our business, including fines or demands or orders that we modify or cease existing business practices. ● The federal Physician Payments Sunshine Act, implemented as the Open Payments Program, which requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children' s Health Insurance Program (with certain exceptions), among others, to track and report annually to CMS information related to direct or indirect payments and other transfers of value they make to U. S.- licensed physicians (defined to include doctors, dentists, optometrists, podiatrists and licensed chiropractors), physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, anesthesiology assistants, certified nurse- midwives, and U. S. teaching hospitals, as well as tracking and reporting of ownership and investment interests held in a company by U. S.- licensed physicians and their immediate family members. **Failure to timely, accurately, and completely submit the required information for all payments, transfers of value and ownership or investment interests may result in civil monetary penalties.** ● Analogous U. S. state and local laws and regulations, such as state anti- kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non- governmental third- party payors, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry' s voluntary compliance guidelines and the relevant ~~compliance~~ **22compliance** guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; state laws that restrict the ability of manufacturers to

offer co- pay support to patients for certain prescription drugs, including information pertaining to and justifying price increases; prohibit prescription drug price gouging; or impose payment caps on certain pharmaceutical products deemed by the state to be " high cost "; state laws that require drug manufacturers to report information related to clinical trials, or information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; state laws that require drug manufacturers to report information on the pricing of certain drugs; state laws and local ordinances that require identification or licensing of sales representatives; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. We will be required to spend substantial time and money to ensure that our business arrangements with third parties comply with applicable healthcare laws and regulations. Even then, governmental authorities may conclude that our business practices do not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If governmental authorities find that our operations violate any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non- compliance with these laws, and we may be required to curtail or restructure our operations. Moreover, we expect that there will continue to be federal and state laws and regulations, proposed and implemented, that could impact our operations and business. In addition, the approval and commercialization of any product candidate we develop outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws. The extent to which future legislation or regulations, if any, relating to health care fraud and abuse laws or enforcement, may be enacted or what effect such legislation or regulation would have on our business remains uncertain. Healthcare ReformThere have been and continue to be a number of healthcare- related legislative and regulatory initiatives and reforms in the United States that significantly affect the pharmaceutical industry. For example, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, the " ACA, " was passed in March 2010 ~~,~~ and substantially changed the way healthcare is financed by both governmental and private insurers and significantly impacted the U. S. pharmaceutical industry. Among other things, the ACA: subjects biologics to potential competition by lower- cost biosimilars; addresses a methodology through which rebates owed by manufacturers under the Medicaid Drug Rebate Program, or " MDRP, " are calculated for covered outpatient drugs that are inhaled, infused, instilled, implanted or injected; increases the minimum Medicaid rebates owed by manufacturers under the MDRP and extends the rebate program to individuals enrolled in Medicaid managed care organizations; and establishes annual fees and taxes on manufacturers of certain branded prescription drugs. ~~26The~~ -- **The** ACA and certain of its provisions have been subject to judicial challenges as well as legislative and regulatory efforts to repeal or replace them or to alter their interpretation or implementation. For example, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, bills affecting the implementation of certain taxes under the ACA have been signed into law. The Tax Cuts and Jobs Act of 2017, or the " Tax Act, " includes a provision that repealed the tax- based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year, commonly referred to as the " individual mandate. " CMS rules issued in 2018 permit further collections and payments to and from certain ACA- qualified health plans and health insurance issuers under the ACA risk adjustment program. The Further Consolidated Appropriations Act of 2020 fully repealed the ACA' s " Cadillac Tax " on certain high- cost employer- sponsored insurance plans and, effective in 2021, the annual fee imposed on certain health insurance providers based on market share. On March 11, 2021, Congress enacted the American Rescue Plan Act of 2021, which included among its provisions a sunset of the ACA' s cap on pharmaceutical manufacturers' rebate liability under the Medicaid Drug Rebate Program. Under the ACA, manufacturers' rebate liability was **previously** capped at 100 % of the average manufacturer price for a covered outpatient drug. ~~Effective~~ **However, as of** January 1, 2024, manufacturers' MDRP rebate liability ~~will~~ **is** no longer ~~be~~ capped, potentially resulting in a manufacturer paying more in MDRP rebates than it receives on the sale of certain covered outpatient drugs. The American Rescue Plan Act also temporarily increased premium tax credit assistance for individuals eligible for subsidies under the ACA for 2021 and 2022 and removed the 400 % federal poverty level limit that otherwise applies for purposes of eligibility to receive premium tax credits. **The Inflation Reduction Act of 2022 (" IRA ") extended 23this increased tax credit assistance and removal of the 400 % federal poverty limit through 2025.** In the future, there may be additional challenges and / or amendments to the ACA. On June 17, 2021, the U. S. Supreme Court dismissed a legal challenge to the ACA brought by several states arguing that, without the individual mandate, the entire ACA was unconstitutional. The Supreme Court dismissed the lawsuit without ruling on the merits of the states' constitutionality arguments. It is unclear how future litigation and ~~the~~ **any** healthcare reform measures of the ~~Biden~~ **Trump** administration will impact the ACA and our business. Additionally, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, several U. S. Congressional inquiries and proposed and enacted pieces of federal and state legislation have been designed to, among other things: bring more transparency to drug pricing; reduce the cost of prescription drugs under government payor programs; review the relationship between pricing and manufacturer patient programs; and reform government program reimbursement methodologies for drugs. Policymakers have also indicated that they will continue to seek legislative and administrative measures to control drug costs. For example, in August 2022, **former** President Biden signed into law the ~~Inflation Reduction Act of 2022 (" IRA ")~~, which implements substantial changes to the Medicare program, including drug pricing reforms and the creation of new Medicare inflation rebates. Namely, the IRA imposes inflation rebates on drug manufacturers for products reimbursed under Medicare Parts B and D if the prices of those products increase faster than inflation; implements changes to the Medicare Part D benefit that, beginning in 2025, ~~will~~ cap beneficiary annual out- of-

pocket spending at $ 2, 000, while imposing new discount obligations for pharmaceutical manufacturers; and, beginning in 2026, establishes a " maximum fair price " for a fixed number of high expenditure pharmaceutical and biological products covered under Medicare Parts B and D following a price negotiation process with CMS. CMS has also taken steps to implement the IRA, including: ~~on June 30~~ **releasing the negotiated maximum prices** , **which will be effective in** ~~2023~~ **2026** , **for** ~~issuing guidance detailing the requirements and parameters of~~ the first ~~round of price negotiations, to take place during 2023 and 2024, for products subject to the " maximum fair price " provision that would become effective in 2026; on August 29, 2023, releasing the initial list of~~ ten drugs **that were** subject to ~~price~~ **the IRA' s** ~~negotiations~~ -- **negotiation process** ~~; on November 17, 2023~~ , releasing **quarterly** ~~guidance outlining the methodology for identifying certain manufacturers eligible to participate in a phase- in period where discounts on applicable products will be lower than those required by the Medicare Part D Manufacturer Discount Program; and on December 14, 2023, releasing a list~~ **lists** of ~~48~~ Medicare Part B products that ~~had an~~ **are subject to** adjusted coinsurance ~~rate~~ **rates** based on the inflationary rebate provisions of the IRA ~~for the time period of January 1~~ , **and announcing a list of fifteen additional drugs that will be subject to price negotiations during** ~~2024~~ **2025** ~~to March 31, 2024~~ . ~~While~~ **However,** it **is unclear** ~~remains to be seen~~ how ~~the drug pricing provisions imposed by~~ the IRA will ~~affect~~ **be implemented or changed under the new Trump Administration, and the degree of impact that the IRA will ultimately have upon** the broader pharmaceutical industry **similarly remains unclear** ~~, several pharmaceutical manufacturers and other industry stakeholders have challenged the law, including through lawsuits brought against the U~~ . ~~S. Department of Health and Human Services, the Secretary of the U. S. Department of Health and Human Services, CMS, and the CMS Administrator challenging the constitutionality and administrative implementation of the IRA' s drug price negotiation provisions~~ . There have also been administrative developments in the U. S. related to drug pricing. **For example** ~~On February 2, 2022, the Biden administration signaled its continued commitment to the Cancer Moonshot initiative, which was initially launched in 2016. In its announcement, the administration noted that its new goals under the initiative include addressing inequities in order to ensure broader access to cutting- edge cancer therapeutics and investing in a robust pipeline for new treatments. In alignment with President Biden' s Cancer Moonshot initiative~~ , on June 27, 2023, the Center for Medicare Innovation at ~~27CMS~~ -- **CMS** announced a new model, the Enhancing Oncology Model, that is designed to make high- quality cancer care more affordable to both patients and Medicare. In addition, on ~~October 14, 2022, President Biden issued an Executive Order on Lowering Prescription Drug Costs for Americans, which instructed the Secretary of the Department of Health and Human Services to consider whether to select for testing by the CMS Innovation Center new health care payment and delivery models that would lower drug costs and promote access to innovative drug therapies for beneficiaries enrolled in the Medicare and Medicaid programs. On~~ February 14, 2023, **HHS** ~~the Department of Health and Human Services~~ issued a report **that** ~~in response to the October 14, 2022, Executive Order, which~~ , among other things, ~~selects~~ **selected** three potential drug affordability and accessibility models to be tested by the CMS Innovation Center. Specifically, the report ~~addresses~~ **addressed** : (1) a model that would allow Part D Sponsors to establish a " high- value drug list " setting the maximum ~~out~~ **co** - **payment amount** ~~of- pocket costs~~ for certain common generic drugs at $ 2 ~~per month per drug~~ ; (2) a Medicaid- focused model that would establish a partnership between CMS, manufacturers, and state Medicaid agencies that would result in multi- state outcomes- based agreements ~~for~~ - **or** certain cell and gene therapy drugs; and (3) a model that would adjust Medicare Part B payment amounts for Accelerated Approval Program drugs to advance the developments of novel treatments. It remains to be seen how these drug pricing initiatives will affect the broader pharmaceutical industry. Individual states in the United States have also increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement limitations, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. Moreover, in May 2018, the Trickett Wendler, Frank Mongiello, Jordan McLinn and Matthew Bellina Right to Try Act of 2017, or the Right to Try Act, was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase 1 clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a pharmaceutical manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act. **The biopharmaceutical industry is subject to extensive regulatory obligations and policies that may be subject to significant and abrupt change, including due to judicial challenges, election cycles, and resulting regulatory updates and changes in policy priorities. For example, on June 28, 2024, the U. S. Supreme Court issued an opinion holding that courts 24reviewing agency action pursuant to the Administrative Procedure Act (" APA ") " must exercise their independent judgment " and " may not defer to an agency interpretation of the law simply because a statute is ambiguous. " The decision will have a significant impact on how lower courts evaluate challenges to agency interpretations of law, including those by CMS and other agencies with significant oversight of the healthcare industry. The new framework is likely to increase both the frequency of such challenges and their odds of success by eliminating one way in which the government previously prevailed in such cases. As a result, significant regulatory policies may be subject to increased litigation and judicial scrutiny. Any resulting changes in regulation may result in unexpected delays, increased costs, or other negative impacts that are difficult to predict but could have a material adverse effect on our business and financial condition. For example, certain of these changes could impose additional limitations on the rates we will be able to charge for our current and future products or the amounts of reimbursement available for our current and future products from governmental agencies or third- party payors.** Human Capital ResourcesAs of December 31, ~~2023~~ **2024** , we had ~~82~~ **43** full- time employees ~~. Based on the announced restructuring of our operations, we plan to have 51 full- time~~

~~employees as of March 21, 2024. This reduction will primarily occur in our manufacturing operations, but also will impact areas of discovery, research, development, clinical, and general administrative~~ . Our success depends upon our ability to retain and attract highly qualified management and technical personnel. We consider the intellectual capital of our employees to be an essential driver of our business and key to our future prospects. Recruiting and retaining qualified employees, consultants and advisors for our business, including scientific and technical personnel, is critical to our success. Competition for skilled personnel is intense and the turnover rate can be high in our industry ~~and we~~ **. We** continue to monitor our turnover rate and the overall supply of skilled labor in the market. We also monitor our compensation programs closely and provide what we consider to be a competitive mix of compensation and benefits for our employees, as well as participation in our equity programs. None of our employees are subject to a collective bargaining agreement or represented by a trade or labor union. Corporate Information and Access to SEC ReportsWe were incorporated in Delaware in September 2015. Our primary executive offices are located at 9000 Virginia Manor Road, Suite 200, Beltsville, Maryland 20705 and our telephone number is (240) 399- 4900. We make available, free of charge, on our website at www. nextcure. com, our annual reports on Form 10- K, quarterly reports on Form 10- Q, current reports on Form 8- K and any amendments to such reports as soon as reasonably practicable after such reports are electronically filed with, or furnished to, the SEC. The contents of our website are not incorporated into this Annual Report. ~~28Item --~~ **Item** 1A. Risk FactorsInvesting in our common stock involves a high degree of risk. You should carefully consider the risks described below together with all of the other information in this Annual Report, including our financial statements and the related notes and the information described in the section entitled " Management' s Discussion and Analysis of Financial Condition and Results of Operations, " before deciding whether to invest in our common stock. If any of the events described below actually occurs, our business, results of operations, financial conditions, cash flows or prospects could be harmed. If that were to happen, the trading price of our common stock could decline, and you could lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations. Risks Related to Our Financial Position and Need for Additional CapitalWe have a limited operating history and no products approved for commercial sale. We have a history of significant losses, expect to continue to incur significant losses for the foreseeable future and may never achieve or maintain profitability. We are a clinical- stage biopharmaceutical company with a limited operating history. Since our founding in 2015, we have incurred significant net losses. Our net losses were $ ~~62~~ **55** . 7 million and $ ~~74~~ **62** . 7 million for the years ended December 31, **2024 and** 2023 ~~and 2022~~ , respectively. As of December 31, ~~2023~~ **2024** , we had an accumulated deficit of $ ~~324~~ **380** . ~~5~~ **1** million. We have funded our operations to date primarily with proceeds from public offerings of our common stock, private placements of our preferred stock and upfront fees received under the Lilly Agreement, which was terminated effective March 2020. Since commencing operations, we have devoted substantially all of our efforts and financial resources to organizing and staffing our company, identifying business development opportunities, raising capital, securing intellectual property rights related to our product candidates, building and optimizing our manufacturing capabilities and conducting discovery, research and development activities for our product candidates. ~~We~~ **25We** expect that it will be several years, if ever, before we have a commercialized product. We expect to continue to incur significant expenses and operating losses for the foreseeable future. The net losses we incur may fluctuate significantly from year to year. We anticipate that our expenses will increase substantially if, and as, we: ● continue to advance the preclinical and clinical development of our existing product candidates and our research programs; ● seek regulatory approvals for any product candidates that successfully complete clinical trials; ● source cGMP manufacture of drug supply necessary for any future, including late stage, clinical trials; ● hire additional clinical, quality control, regulatory, scientific and administrative personnel; ● expand our operational, financial and management systems and increase personnel, including to support our clinical development, manufacturing and commercialization efforts and our operations as a public company; ● maintain, expand and protect our intellectual property portfolio; ● establish a marketing, sales, distribution and medical affairs infrastructure to commercialize any products for which we may obtain marketing approval and commercialize, whether on our own or jointly with a partner; ● acquire or in- license other technologies or engage in strategic partnerships; and ● incur additional legal, accounting or other expenses in operating our business. To become and remain profitable, we, whether on our own or jointly with any potential future collaborator, must develop and eventually commercialize products with significant market potential. We will need to be successful in a range of challenging activities, including completing preclinical studies and clinical trials, obtaining marketing approval for product candidates, manufacturing, marketing and selling products and satisfying any post- marketing requirements. We ~~29may --~~ **may** never succeed in any or all of these activities and, even if we do, we may never generate revenue that is significant or large enough to achieve profitability. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment. We have never generated revenue from product sales and may never be profitable. Our ability to generate revenue from product sales and achieve profitability depends on our ability, alone or with collaboration partners, to successfully complete the development of, and obtain the regulatory approvals necessary to commercialize, our product candidates. We do not anticipate generating revenue from product sales for the next several years, if ever. Our ability to generate future revenue from product sales depends heavily on our, or our potential future collaborators', success in: ● completing preclinical studies and clinical trials of our product candidates, including our ongoing Phase 1 ~~/ 2~~ clinical trial for ~~NC410~~ **LNCB74** ; ● seeking and obtaining marketing approvals for any product candidates that we or our collaborators develop; ● receiving acceptance of INDs for future product candidates; ● identifying and developing new product candidates; ● launching and commercializing product candidates for which we obtain marketing approval by establishing a marketing, sales, distribution and medical affairs infrastructure or, alternatively, collaborating with a commercialization partner; **26** ● achieving coverage and adequate reimbursement by hospitals and third- party payors, including governmental authorities, such as

Medicare and Medicaid, private insurers and managed care organizations, for product candidates, if approved, that we or our collaborators develop; ● manufacturing cGMP supply of our product candidates for clinical trials and, if approved, commercial sales; ● obtaining market acceptance of product candidates, if approved, that we develop as viable treatment options; ● addressing any competing technological and market developments; ● negotiating favorable terms in any collaboration, licensing or other arrangements into which we may enter and performing our obligations under such arrangements; ● maintaining, protecting and expanding our portfolio of intellectual property rights, including patents, trade secrets and know- how; ● defending against third- party interference or infringement claims, if any; and ● attracting, hiring and retaining qualified personnel. We anticipate incurring significant costs associated with commercializing any product candidate that is approved for commercial sale. Our expenses could increase beyond expectations if we are required by the FDA or other regulatory agencies to perform clinical trials or studies in addition to those that we currently anticipate. Even if we are able to generate revenue from the sale of any approved products, we may not become profitable and may need to obtain additional funding to continue operations. ~~30We~~ **We** will require substantial additional financing to pursue our business objectives, which may not be available on acceptable terms, or at all. A failure to obtain this necessary capital when needed could force us to delay, limit, reduce or terminate our product development, commercialization efforts or other operations. Our operations have consumed substantial amounts of cash since inception. We expect to continue to spend substantial amounts to continue the preclinical and clinical development of our current and future programs. If we receive marketing approval for any product candidates, including ~~NC410, or~~ LNCB74 **,** we will require significant additional amounts of cash in order to launch and commercialize such product candidates. In addition, other unanticipated costs may arise. Because the designs and outcomes of our planned and anticipated clinical trials are highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development of and commercialize any product candidate we develop. Our future capital requirements depend on many factors, including: ● the scope, progress, timing, results and costs of researching and developing ~~NC410,~~ LNCB74 and our other product candidates, and of conducting preclinical studies and clinical trials; ● the timing of, and the costs involved in, obtaining marketing approval for ~~NC410,~~ LNCB74 and any future product candidates we develop, if clinical trials are successful; ● the costs of manufacturing ~~NC410,~~ LNCB74 and any future product candidates for preclinical studies and clinical trials and in preparation for marketing approval and commercialization; ● the costs of commercialization activities, including marketing, sales and distribution costs, for ~~NC410,~~ LNCB74 and any future product candidates we develop, whether alone or with a collaborator, if any of these product candidates are approved for sale; ● our ability to establish and maintain additional strategic collaborations, licensing or other arrangements on favorable terms, if at all; **27** ● the costs involved in preparing, filing, prosecuting, maintaining, expanding, defending and enforcing patent claims, including litigation costs and the outcome of any such litigation; ● our current collaboration and license agreements remaining in effect and our achievement of milestones and the timing and amount of milestone payments we are required to make, or that we may be eligible to receive, under those agreements; ● the timing, receipt and amount of sales of, or royalties on, our future products, if any; and ● the emergence of competing therapies and other developments in the oncology market. Unless and until we generate sufficient product and royalty revenue to finance our cash requirements, we expect to finance our future cash needs through a combination of public or private equity offerings, debt financings, marketing and distribution arrangements, other collaborations, strategic alliances and licensing arrangements. As of December 31, ~~2023~~ **2024** , we had $ ~~108~~ **68** . ~~3~~ **6** million in cash, cash equivalents and marketable securities. Based on our research and development plans, we expect that our existing cash, cash equivalents and marketable securities will enable us to fund our operating expenses and capital expenditure requirements into the second half of 2026. This estimate is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we expect. Changes may occur within or beyond our control that would cause us to consume our available capital before that time, including changes in and progress of our development activities, acquisitions of additional product candidates and changes in regulation. If we raise additional capital through marketing, sales and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish certain valuable rights to our product candidates, future revenue streams, research programs or technologies or grant licenses on terms that may not be favorable to us. If we raise additional capital through public or private equity offerings, the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. Further, to the extent that we raise ~~31additional~~ -- **additional** capital through the sale of common stock or securities convertible or exchangeable into common stock, your ownership interest will be diluted. If we raise additional capital through debt financing, we would be subject to fixed payment obligations and may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Adequate additional financing may not be available to us on acceptable terms, or at all. If we are unable to obtain additional financing on favorable terms when needed, we may be required to delay, limit, reduce or terminate preclinical studies, clinical trials, or other research and development activities or one or more of our development programs. Risks Related to the Discovery and Development of Our Product CandidatesAs an organization, we have limited experience designing and implementing clinical trials, and we have never conducted pivotal clinical trials. Failure to adequately design a trial, or incorrect assumptions about the design of the trial, could adversely affect the ability to initiate the trial, enroll patients, complete the trial, or obtain regulatory approval on the basis of the trial results, as well as lead to increased or unexpected costs and in delayed timelines. The design and implementation of clinical trials is a complex process. We have limited experience designing and implementing clinical trials, and we may not successfully or cost- effectively design and implement clinical trials that achieve our desired clinical endpoints efficiently, or at all. A clinical trial that is not well designed may delay or prevent initiation or completion of the trial, can lead to increased difficulty in enrolling patients, may make it more difficult to obtain regulatory approval for the product candidate on the basis of the study results, or, even if a product candidate is approved, could make it more difficult to commercialize the product successfully or obtain reimbursement from third- party payors. Additionally, a trial that is not well- designed could be inefficient or more expensive than it otherwise would have been,

or we may incorrectly estimate the costs to implement the clinical trial, which could lead to a shortfall in funding. If we select an incorrect dose or dose administration schedule, that could negatively impact the results of the trial, including if we select doses that are too low to be effective or administer doses too infrequently based on the half- life of the active ingredient. We also expect to continue to rely on third parties to conduct our pivotal clinical trials (see " Risks Related to Reliance on Third Parties "). We rely, or will rely, on third parties to help conduct our ongoing and planned preclinical studies and clinical trials for ~~NC410, NC525,~~ LNCB74 and any future product candidates we develop. If these third parties do not successfully carry out their contractual duties, comply with regulatory requirements or meet expected deadlines, we may not be able to obtain marketing approval for or commercialize ~~NC410, NC525,~~ LNCB74 and any future product candidates we develop, ~~and~~ **28and** our business could be materially harmed. Consequently, we may be unable to successfully and efficiently execute and complete clinical trials that are required for BLA submission and FDA approval of ~~NC410, NC525,~~ LNCB74 or future product candidates. We may require more time and incur greater costs than our competitors and may not succeed in obtaining regulatory approvals of product candidates that we develop. Our business is dependent on our ability to advance our current and future product candidates through clinical trials, obtain marketing approval and ultimately commercialize them. We are early in our development efforts. We initiated our first clinical trial for ~~NC410 in June 2020, and plan to file our~~ LNCB74 **in January** ~~IND by year end 2024~~ **2025** . Our ability to generate product revenues, which we do not expect will occur for several years, if ever, will depend heavily on the successful development and eventual commercialization of ~~NC410,~~ LNCB74 and any future product candidates we develop, which may never occur. Our current product candidates and any future product candidates we develop will require additional preclinical or clinical development, management of clinical, preclinical and manufacturing activities, marketing approval in the United States and other jurisdictions, demonstration of effectiveness to pricing and reimbursement authorities, sufficient cGMP manufacturing supply for both preclinical and clinical development and commercial production, building of a commercial organization and substantial investment and significant marketing efforts before we generate any revenues from product sales. The clinical and commercial success of our current and future product candidates will depend on several factors, including the following: ● timely and successful completion of preclinical studies and our clinical trials; ● sufficiency of our financial and other resources to complete the necessary preclinical studies and clinical trials; ~~32~~ ● acceptance of INDs for any future product candidates; ● successful enrollment in and completion of clinical trials; ● successful data from our clinical program that supports an acceptable risk- benefit profile of our product candidates in the intended patient populations; ● our ability to consistently manufacture our product candidates on a timely basis or to establish agreements with third- party manufacturers, if needed; ● whether we are required by the FDA or comparable foreign regulatory authorities to conduct additional clinical trials or other studies beyond those planned or anticipated to support approval of our product candidates; ● acceptance of our proposed indications and the primary endpoint assessments evaluated in the clinical trials of our product candidates by the FDA and comparable foreign regulatory authorities; ● receipt and maintenance of timely marketing approvals from applicable regulatory authorities; ● successfully launching commercial sales of our product candidates, if approved; ● the prevalence, duration and severity of potential side effects or other safety issues experienced with our product candidates, if approved; ● entry into collaborations to further the development of our product candidates; ● obtaining and maintaining patent and trade secret protection or regulatory exclusivity for our product candidates; **29** ● acceptance of the benefits and uses of our product candidates, if approved, by patients, the medical community and third- party payors; ● maintaining a continued acceptable safety, tolerability and efficacy profile of the product candidates following approval; ● our compliance with any post-approval requirements imposed on our products, such as post- marketing studies, a REMS or additional requirements that might limit the promotion, advertising, distribution or sales of our products or make the products cost- prohibitive; ● competing effectively with other therapies; ● obtaining and maintaining healthcare coverage and adequate reimbursement from third- party payors; ● our ability to identify targets and therapies, through our collaborative relationships, or otherwise; and ● enforcing and defending intellectual property rights and 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, and could otherwise materially harm our business. Successful completion of preclinical studies and clinical trials does not mean that ~~NC410,~~ LNCB74 or any future product candidates we develop will receive regulatory approval. Even if regulatory approvals are obtained, we could experience significant delays or an inability to successfully commercialize our current and any future product candidates we develop, which would materially harm our business. If we are not able to generate sufficient revenue through the sale of any current or future product candidate, we may not be able to continue our business operations or achieve profitability. ~~33The~~ -- **The** regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time- consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be materially harmed. The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate' s clinical development and may vary among jurisdictions. We have not obtained regulatory approval for any product candidate. Neither we nor any future collaborator is permitted to market any biological product in the United States until we or the future collaborator receives regulatory approval of a BLA from the FDA. It is possible that none of our current or future product candidates will ever obtain regulatory approval from the FDA or comparable foreign regulatory authorities. Our current and 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 a product candidate is safe, pure and potent for its proposed indication; ● the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval; ● we may be unable to demonstrate that a

product candidate' s clinical and other benefits outweigh its safety risks; **30** ● the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from clinical trials or preclinical studies; ● the data collected from clinical trials of our product candidates may not be sufficient to support the submission of a BLA to the FDA or regulatory submissions to comparable regulatory authorities to obtain regulatory approval in such jurisdiction; and ● the FDA or comparable foreign regulatory authorities may find deficiencies with or fail to approve our manufacturing processes or facility or the manufacturing processes or facilities of third- party manufacturers with which we contract for clinical and commercial supplies. This lengthy approval process as well as the unpredictability of clinical trial results may result in our failing to obtain regulatory approval to market any product candidate we develop, which would significantly harm our business, results of operations and prospects. The FDA and other comparable foreign authorities have substantial discretion in the approval process and in determining when or whether regulatory approval will be granted for any product candidate that we develop. Even if we believe the data collected from current or future clinical trials of our product candidates are promising, such data may not be sufficient to support approval by the FDA or any other regulatory authority. In addition, even if we were to obtain approval, the FDA may approve any of our product candidates for fewer or more limited indications, or a more limited patient population, than we request, may grant approval contingent on the performance of costly clinical trials, development of an in vitro companion diagnostic, or other post- marketing requirements, or may approve a product candidate with a label that does not include the labeling claims we believe are necessary or desirable for the successful commercialization of such product candidates. The FDA or comparable foreign regulatory authorities may change their policies, promulgate additional regulations, revise existing regulations or take other actions that may prevent or delay approval of our future products under development on a timely basis. Such policy or regulatory changes could impose additional requirements upon us that could delay our ability to obtain approvals, increase the costs of compliance or restrict our ability to maintain any ~~34marketing~~ **marketing** authorizations we may have obtained. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates. Clinical development involves a lengthy and expensive process with uncertain outcomes. We may incur additional costs and experience delays in developing and commercializing or be unable to develop or commercialize our current and future product candidates. To obtain the requisite regulatory approvals to commercialize any of our product candidates, we must demonstrate through extensive preclinical studies and clinical trials that our product candidates are safe, pure and potent in humans. Clinical testing is expensive and can take many years to complete, and its outcome is highly uncertain. Failure can occur at any time during the clinical trial process, and our future clinical trial results may not be successful. We may experience delays in completing our clinical trials or preclinical studies and initiating or completing our planned clinical trials and development efforts. Additionally, we cannot be certain the ongoing and planned preclinical studies or clinical trials for ~~NC410,~~ LNCB74 or any future product candidates will begin on time, not require redesign, enroll an adequate number of subjects on time or be completed on schedule, if at all. For example, we announced in December 2023 that based on current efficacy data and prioritization, we had decided to discontinue our monotherapy Phase 2 clinical trial for NC762. We may also experience numerous unforeseen events during our clinical trials that could delay or prevent our ability to receive marketing approval or commercialize the product candidates we develop, including: ● results from preclinical studies or clinical trials may not be predictive of results from later clinical trials of any product candidate; ● the FDA or other regulatory authorities, IRBs or independent ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site; ● the FDA or other regulatory authorities may require us to submit additional data such as long- term toxicology studies, or impose other requirements on us, before permitting us to initiate a clinical trial; **31** ● we may experience delays in reaching, or fail to reach, agreement on acceptable terms with prospective trial sites and prospective contract research organizations, or " CROs ", as the terms of these agreements can be subject to extensive negotiation and vary significantly among different CROs and trial sites; ● clinical trials of any product candidate may fail to show safety, purity or potency, or may produce negative or inconclusive results, which may cause us to decide, or regulators to require us, to conduct additional nonclinical studies or clinical trials or which may cause us to decide to abandon product candidate development programs; ● the number of patients required for clinical trials may be larger than we anticipate or we may have difficulty in recruiting and enrolling patients to participate in clinical trials, including as a result of the size and nature of the patient population, the proximity of patients to clinical trial sites, eligibility criteria for the clinical trial, the nature of the clinical trial protocol, the availability of approved effective treatments for the relevant disease, competition from other clinical trial programs for similar indications and clinical trial subjects and the impact of public health emergencies, such as the COVID- 19 pandemic; ● it may be difficult to enroll a sufficient number of patients, enrollment in these clinical trials may be slower than we anticipate, or participants may drop out of these clinical trials or may fail to return for post- treatment follow- up at a higher rate than we anticipate; ● our CROs and other third- party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, or may deviate from the clinical trial protocol or drop out of the trial, which may require that we add new clinical trial sites or investigators; ● we may elect to, or regulators, IRBs or ethics committees may require that we or our investigators, suspend or terminate clinical research or trials for various reasons, including noncompliance with regulatory requirements or a finding that participants are being exposed to unacceptable health risks; ~~35~~ ● any of our product candidates could cause undesirable side effects that could result in significant negative consequences, including the inability to enter clinical development or receive regulatory approval; ● the cost of preclinical or nonclinical testing and studies and clinical trials of any product candidates may be greater than we anticipate; ● we may face hurdles in addressing subject safety concerns that arise during the course of a trial, causing us or our investigators, regulators, IRBs or ethics committees to suspend or terminate trials, or reports may arise from nonclinical or clinical testing of other cancer therapies that raise safety or efficacy concerns about our product candidates; ● the supply, quality or timeliness of delivery of materials for product candidates we develop or other materials necessary to conduct clinical trials may be insufficient or inadequate; and ● we, or third parties on whom we are dependent, may suffer business interruptions resulting from geo-

political actions, including war and terrorism, or natural disasters and public health emergencies, such as the COVID- 19 pandemic. We may encounter delays if a clinical trial is suspended or terminated by us, the IRBs of the institutions in which such trials are being conducted or ethics committees, or the DSMB recommends suspension or termination for such trial or by the FDA or other regulatory authorities. Such authorities may impose such a suspension or termination 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 or lack of adequate funding to continue the clinical trial. Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of marketing approval of our product candidates. The FDA or other regulatory authorities may disagree with our clinical trial design and our interpretation of data from clinical trials or may change the ~~requirements~~ **32requirements** for approval even after they have reviewed and commented on the design for our clinical trials. In addition, factors outside our control, such as government shutdowns, natural disasters and public health emergencies such as the COVID- 19 pandemic, could disrupt business at the FDA or other regulatory authorities, which could result in delays of reviews, approvals and communications with regulatory authorities related to our clinical trials and product candidates. Principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and may receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, or a regulatory authority concludes that the financial relationship may have affected the interpretation of the trial, the integrity of the data generated at the applicable clinical trial site may be questioned and the utility of the clinical trial itself may be jeopardized, which could result in the delay or rejection of the marketing application we submit. Any such delay or rejection could prevent or delay us from commercializing our current or future product candidates. If we experience delays in the completion, or termination, of any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed and our ability to generate product revenues from any of these product candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down the development and approval process for our product candidates and jeopardize our ability to commence product sales and generate revenues. Significant clinical trial delays could also allow our competitors to bring products to market before we do or shorten any periods during which we have the exclusive right to commercialize our product candidates. Any such events would impair our ability to successfully commercialize our product candidates and may harm our business and results of operations. Any of these occurrences may significantly harm our business, financial condition and prospects. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates or result in the development of our product candidates stopping early. ~~36Preclinical -~~ **Preclinical** development is uncertain. Our preclinical programs may experience delays or may never advance to clinical trials, which would adversely affect our ability to obtain regulatory approvals or commercialize these programs on a timely basis or at all. With the exception of **LNCB74,** NC410, NC525 and NC318, all of our product candidates are still in the preclinical stage, and the risk of failure for such product candidates is high. In order to obtain FDA approval to market a new biologic we must demonstrate proof of safety, purity and potency, including efficacy, in humans. To meet these requirements, we will have to conduct adequate and well- controlled clinical trials. Before we can commence clinical trials for a product candidate, we must complete extensive preclinical testing and studies that support our planned clinical trials in humans. We cannot be certain of the timely completion or outcome of our preclinical testing and studies and cannot predict if the FDA will accept our proposed clinical programs or if the outcome of our preclinical testing and studies will ultimately support the further development of our current or future product candidates. As a result, we cannot be sure that we will be able to submit INDs or similar applications for our preclinical programs on the timelines we expect, if at all, and we cannot be sure that submission of INDs or similar applications will result in the FDA or other regulatory authorities allowing clinical trials to begin. Conducting preclinical testing is a lengthy, time- consuming and expensive process. The length of time of such testing may vary substantially according to the type, complexity and novelty of the program, and often can be several years or more per program. Delays associated with programs for which we are conducting preclinical testing and studies may cause us to incur additional operating expenses. Moreover, we may be affected by delays associated with the preclinical testing and studies of certain programs that are the responsibility of our potential future collaborators over which we have no control. The commencement and rate of completion of preclinical studies and clinical trials for a product candidate may be delayed by many factors, including but not limited to: ● an inability to generate sufficient preclinical or other in vivo or in vitro data to support the initiation of clinical studies; ● delays in reaching a consensus with regulatory agencies on study design; and ● the FDA not permitting the reliance on preclinical or other data from published scientific literature. ~~Interim -~~ **33Interim** and preliminary results from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit, validation and verification procedures that could result in material changes in the final data. From time to time, we may publish interim data, including interim top- line results or preliminary results from our clinical trials. Interim data and results from our clinical trials 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. For example, notwithstanding the durable responses initially observed in our ongoing Phase 1 / 2 clinical trial of NC318 in NSCLC, we announced in November 2022 that based upon then- current efficacy data we decided to discontinue our Phase 2 clinical trial for NC318 monotherapy. Preliminary or top- line results also remain subject to audit, validation and verification procedures that may result in the final data being materially different from the interim and preliminary data we previously published. **There is a high failure rate for drugs and biologics proceeding through clinical trials.** As a result, interim and preliminary data may not be predictive of final results and should be viewed with caution until the final data are available. Differences between preliminary or interim data and final data could significantly harm our business prospects and

may cause the trading price of our common stock to fluctuate significantly ~~. Initial positive trial results and results from preclinical studies and early- stage clinical trials may not be predictive or indicative of results when the trial is completed or in later stage trials. The results of preclinical studies may not be predictive of the results of clinical trials. Preclinical studies and early- stage clinical trials are primarily designed to test safety, to study pharmacokinetics and pharmacodynamics and to understand the side effects of product candidates at various doses and schedules, and the results of any early- stage clinical trials may not be predictive of the results of later- stage, large- scale efficacy clinical trials. In addition, initial success in clinical trials may not be indicative of results obtained when such trials are completed. There can be no assurance that any of our current or future clinical trials will ultimately be successful or support further clinical development of any of our product candidates. There is a high failure rate for drugs and biologics proceeding through clinical trials. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in clinical development 37even after achieving promising results in earlier studies, and any such setbacks in our clinical development could have a material adverse effect on our business and operating results~~ . Even if our clinical trials are completed, the results may not be sufficient to obtain regulatory approval for our product candidates. Data obtained from preclinical and clinical activities are subject to varying interpretations, which may delay, limit or prevent regulatory approval. In addition, the results of our preclinical studies may not be predictive of the results of outcomes in human clinical trials. For example, our current or future product candidates may demonstrate different chemical, biological and pharmacological properties in patients than they do in laboratory studies or may interact with human biological systems in unforeseen or harmful ways. Product candidates in later stages of clinical trials may fail to show desired pharmacological properties or produce the necessary safety and efficacy results despite having progressed through preclinical studies and initial clinical trials. Even if we are able to initiate and complete clinical trials, the results may not be sufficient to obtain regulatory approval for our product candidates. In addition, we may experience regulatory delays or rejections as a result of many factors, including changes in regulatory policy during the period of our product candidate development. Any such delays could negatively impact our business, financial condition, results of operations and prospects. Because the numbers of subjects in our Phase 1 / 2 and Phase 1 clinical trials are small, the results from each of these trials, once completed, may be less reliable than results achieved in larger clinical trials. A study design that is considered appropriate includes a sufficiently large sample size with appropriate statistical power, as well as proper control of bias, to allow a meaningful interpretation of the results. The preliminary results of studies with smaller sample sizes, such as our Phase 1 ~~/ 2~~ clinical trial of **LNCB74** ~~NC410 Combo~~ , can be disproportionately influenced by the impact the treatment had on a few individuals, which limits the ability to generalize the results across a broader community, thus making the study results less reliable than studies with a larger number of subjects and making it difficult to predict final results from preliminary results. As a result, there may be less certainty that the respective investigational drug product would achieve a statistically significant effect in any future clinical trials. **In ongoing** ~~If we conduct any future~~ clinical trials of ~~NC410 Combo, or~~ LNCB74 we may not achieve a statistically significant result or the same level of statistical significance seen, if any, in our Phase 1 ~~/ 2~~ clinical trial. Similarly, if we conduct a clinical trial of any other product candidate we develop with a small sample size, the results of any such trial may be less reliable than results achieved in larger clinical trials and may provide less certainty of achieving statistically significant effects in any future clinical trials. Our approach to the discovery and development of product candidates using our FIND platform is unproven and may not result in marketable products. The success of our business depends in part upon our ability to identify targets based on our proprietary FIND platform and to develop and commercialize medicines. Our approach to the discovery of targets and development of products using the FIND platform is novel. We have not yet initiated or completed a clinical trial of any product candidate developed for a target identified from the FIND platform. The platform may fail to accurately identify targets that modulate the immune system and are appropriate for therapies. Even if we are able to identify targets from the FIND platform and to develop corresponding product candidates, we cannot assure that such product candidates will achieve marketing approval to safely and effectively treat cancer or other disease states. ~~If~~ **34If** we uncover any previously unknown risks related to our FIND platform, or if we experience unanticipated problems or delays in developing our FIND product candidates, we may be unable to achieve our strategy of building an oncology pipeline of novel targets for new therapies focused on non-responders. Our current or future product candidates may cause undesirable side effects or have other properties when used alone or in combination with other approved products or investigational new drugs that could halt their clinical development, delay or prevent their regulatory approval, limit their commercial potential or result in significant negative consequences. Before obtaining regulatory approvals for the commercial sale of our product candidates, we must demonstrate through lengthy, complex and expensive preclinical testing and clinical trials that our product candidates are safe, pure and potent for use in each target indication, and failures can occur at any stage of testing. As with most biologics, use of our current or future product candidates could be associated with side effects or adverse events which can vary in severity ~~38from~~ -- **from** minor reactions to death and in frequency from infrequent to prevalent. There have been serious adverse side effects reported in response to immunotherapies in oncology. Possible adverse side effects that could occur with treatment with therapies include an immunologic reaction early after administration that, while not necessarily adverse to the patient' s health, could substantially limit the effectiveness of the treatment. In addition to any potential side effects caused by the product or product candidate, the administration process or related procedures also can cause adverse side effects. If unacceptable adverse events occur, our clinical trials or any future marketing authorization could be suspended or terminated. If unacceptable side effects arise in the development of our product candidates, the DSMB may recommend or, we, the FDA, or the IRBs at the institutions in which our studies are conducted could suspend or terminate our clinical trials or the FDA or comparable foreign regulatory authorities could order us to cease clinical trials or deny approval of our product candidates for any or all targeted indications. Treatment-related side effects could also affect patient recruitment or the ability of enrolled patients to complete any of our clinical trials 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 our product candidates to understand the side effect

profiles for our clinical trials and upon any commercialization of any of our product candidates. Inadequate training in recognizing or managing the potential side effects of our product candidates could result in patient injury or death. Any of these occurrences may significantly harm our business, financial condition and prospects. Although our current and future product candidates have undergone and will undergo safety testing to the extent possible and, where applicable, under such conditions discussed with regulatory authorities, not all adverse effects of drugs can be predicted or anticipated. Our current and future product candidates could lead to serious side effects that we only discover in clinical trials or during commercial marketing. Unforeseen side effects could arise either during clinical development or after our product candidates have been approved by regulatory authorities and the approved product has been marketed, resulting in the exposure of additional patients. So far, we have not demonstrated that NC410, LNCB74 or any other product candidate is safe in humans, and we cannot predict if ongoing or future clinical trials will do so. If any of our current or future product candidates fail to demonstrate safety and efficacy in clinical trials or do not gain marketing approval, we will not be able to generate revenue and our business will be harmed. In addition, we are ~~ourself~~ **ourselves** studying NC410 in combination with other therapies, supporting Yale' s study of NC318 in combination with other therapies, and may develop LNCB74 and future product candidates in combination with other therapies, which exposes us to additional risks relating to undesirable side effects or other properties. For example, the other therapies may lead to toxicities that are improperly attributed to our product candidates or the combination of our product candidates with other therapies may result in toxicities that the product candidate or other therapy does not produce when used alone. The other therapies we are using in combination may be removed from the market, or we may not be able to secure adequate quantities of such materials for which we have no guaranteed supply contract, and thus be unavailable for testing or commercial use with any of our approved products. The other therapies we may use in combination with our product candidates may also be supplanted in the market by newer, safer or more efficacious products or combinations of products. Even if we successfully advance one of our product candidates through clinical trials, such trials will likely only include a limited number of subjects and limited duration of exposure to our product candidates. As a result, we cannot be assured that adverse effects of our product candidates will not be uncovered when a significantly larger number of patients ~~are~~ **35are** exposed to the product candidate. Further, any clinical trial may not be sufficient to determine the effect and safety consequences of taking our product candidates over a multi- year period. If any of our product candidates receives marketing approval, and we or others later identify undesirable side effects caused by such products, a number of potentially significant negative consequences could result, including: ● regulatory authorities may withdraw their approval of the product; ● we may be required to recall a product or change the way such product is administered to patients; ● additional restrictions may be imposed on the marketing of the particular product or the manufacturing processes for the product or any component thereof; ~~39~~ ● regulatory authorities may require the addition of labeling statements, such as a " black box " warning or a contraindication; ● we may be required to implement a 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; ● we may be subject to fines, warning letters, or other regulatory enforcement action; ● we may be subject to injunctions or the imposition of civil or criminal penalties; ● we may be required to conduct additional post- market clinical trials to assess the safety of the product; ● we may be subject to product seizure or detention, or refusal to permit the import or export of products; ● FDA may refuse to approve pending applications or supplements to approved applications filed by us; ● the product may become less competitive; and ● our reputation may suffer. Any of the foregoing events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and result in the loss of significant revenues, which would materially harm our business. In addition, if one or more of our product candidates or our immunotherapeutic development approach generally prove to be unsafe, our entire technology platform ~~and pipeline~~ could be affected, which would also materially harm our business. If there are difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise be adversely affected. The successful and timely completion of clinical trials in accordance with their protocols depends on, among other things, our ability to enroll a sufficient number of patients who remain in the trial until the trial' s conclusion, including any follow- up period. We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons. For example, we experienced a slowdown of enrollment in our clinical trials as a result of the COVID- 19 pandemic. The enrollment of patients depends on many factors, including: ● the patient eligibility criteria defined in the protocol; ● the nature and size of the patient population required for analysis of the trial' s primary endpoints and the process for identifying patients; ● the number and location of participating clinical sites or patients; **36** ● the design of the trial; ● our ability to recruit clinical trial investigators with the appropriate competencies and experience; ● clinicians' and patients' perceptions as to the potential advantages and risks of the product candidate being studied in relation to other available therapies, including any new products that may be approved for the indications we are investigating; ● the availability of competing commercially available therapies and other competing drug candidates' clinical trials; ● our ability to obtain and maintain patient informed consents for participation in our clinical trials; ~~40~~ ● the risk that patients enrolled in clinical trials will drop out of the trials before completion or, because they may be late- stage cancer patients, will not survive the full terms of the clinical trials; and ● factors outside of our control, including as a result of business interruptions resulting from natural disasters, geo- political developments, and public health emergencies, such as the COVID- 19 pandemic. In addition, our clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as our current and potential future product candidates. This competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial conducted by one of our competitors. Because the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such sites. Moreover, because our current and potential future product candidates may represent a departure from more commonly used methods for cancer treatment, potential patients and their doctors may be inclined to use conventional therapies, such as chemotherapy, rather than enroll patients in our ongoing or any future clinical trial. Delays from

difficulties in patient enrollment in a clinical trial may result in increased costs or affect the timing, outcome or completion of the trial, which could delay or prevent our receipt of regulatory approval of the applicable product candidate or to abandon the trial altogether. We may be required to suspend, repeat or terminate our clinical trials if they are not conducted in accordance with regulatory requirements, the results are negative or inconclusive or the trials are not well designed. Clinical trials must be conducted in accordance with the FDA' s current cGCP or analogous requirements of applicable foreign regulatory authorities. Clinical trials are subject to oversight by the FDA, other foreign governmental agencies and IRBs or ethical committees at the study sites where the clinical trials are conducted. In addition, clinical trials must be conducted with product candidates manufactured in accordance with applicable cGMP. Clinical trials may be suspended by the FDA, other foreign regulatory authorities, us, or by an IRB or ethics committee with respect to a particular clinical trial site, for various reasons, including: ● deficiencies in the conduct of the clinical trials, including failure to conduct the clinical trial in accordance with regulatory requirements or study protocols; ● deficiencies in the clinical trial operations or trial sites; ● unforeseen adverse side effects or the emergence of undue risks to study subjects; ● deficiencies in the trial design necessary to demonstrate efficacy; ● the product candidate may not appear to offer benefits over current therapies; or ● the quality or stability of the product candidate may fall below acceptable standards. ~~We~~ **37We** have chosen to prioritize development of ~~NC410 and~~ LNCB74. We may expend our limited resources on product candidates or indications that do not yield a successful product and fail to capitalize on other candidates or indications for which there may be a greater likelihood of success or may be more profitable. Because we have limited resources, we have strategically determined to prioritize development of ~~NC410 and~~ LNCB74 rather than other product candidates based, in part, on the significant resources required for developing and manufacturing therapies. To date, no regulatory authority has granted approval for a therapy targeting ~~the LAIR pathway or~~ B7- H4. As a result, we may be foregoing other potentially more profitable therapies or therapies or those with a greater likelihood of success. Our decisions concerning the allocation of research, development, collaboration, management and financial resources toward particular product candidates or therapeutic areas may not lead to the development of any viable commercial product and may divert resources away from better opportunities. Similarly, our potential decisions to delay, terminate or collaborate with third parties with respect to, certain programs may subsequently also prove to be suboptimal and could cause us to miss valuable opportunities. If we make incorrect determinations regarding the viability or market ~~41potential~~ -- **potential** of any of our current or future product candidates or misread trends in the oncology or biopharmaceutical industry, our business, financial condition and results of operations could be materially adversely affected. As a result, we may fail to capitalize on viable commercial products or profitable market opportunities, be required to forego or delay pursuit of opportunities with other product candidates or other diseases and disease pathways that may later prove to have greater commercial potential than those we choose to pursue, or relinquish valuable rights to such product candidates through collaboration, licensing or other royalty arrangements in cases in which it would have been advantageous for us to invest additional resources to retain development and commercialization rights. We may need to develop, or enter into a collaboration or partnership to develop, complementary or companion diagnostics for our current or future product candidates. If we, or our future collaborators, are unable to successfully develop complementary or companion diagnostics, or experience significant delays in doing so, we may not realize the full commercial potential of our current or future product candidates. One of the key elements of our product development strategy is to identify cancer patient populations that may derive meaningful benefit from our current or future product candidates. Because predictive biomarkers are being and may be used to identify the right patients for current or future product candidates, we believe that our success may depend, in part, on our ability to develop complementary or companion diagnostics in collaboration with partners. We have limited experience in the development of diagnostics and, as such, we may rely in part on future collaborators in developing appropriate diagnostics to pair with our current or future product candidates. We have not yet begun substantial discussions with any potential partners with respect to the development of complementary or companion diagnostics and may be unsuccessful in entering into collaborations for the development of any such diagnostics for our current or future product candidates. Companion diagnostics are subject to regulation by the FDA and similar comparable foreign regulatory authorities as medical devices and require separate regulatory approval or clearance prior to commercialization. Complementary diagnostics may be subject to regulation by CMS or the FDA and similar comparable foreign regulatory authorities and may require separate regulatory approval or clearance prior to commercialization. Gaining regulatory approval could be time consuming and costly and could delay regulatory approval of the related product candidate. We and our collaborators may encounter difficulties in developing such tests, including issues relating to the selectivity or specificity of the diagnostic, analytical validation, reproducibility or clinical validation. If we, our collaborators, or any third parties that we engage to assist us, are unable to successfully develop complementary or companion diagnostics for our current or future product candidates or experience delays in doing so: ● development of our current or future product candidates may be adversely affected if we are unable to appropriately select patients for enrollment in our clinical trials; and ● we may not realize the commercial potential of our current or future product candidates if, among other reasons, we are unable to appropriately identify, or it takes us longer to identify, patients who are likely to benefit from therapy with our products, if approved. If any of these events were to occur, our business could be materially harmed. ~~Risks~~ **38Risks** Related to the Regulatory Approval and Commercialization of Product Candidates and Other Legal Compliance MattersWe may be unable to obtain FDA approval of our product candidates under applicable regulatory requirements. The denial or delay of any such approval would prevent or delay commercialization of our product candidates and adversely impact our potential to generate revenue, our business and our results of operations. To gain approval to market our product candidates in the United States, we must provide the FDA with clinical data that adequately demonstrate the safety, purity and potency, including efficacy, of the product candidate for the proposed indication or indications in a BLA submission. Product development is a long, expensive and uncertain process, and delay or failure can occur at any stage of any of our clinical development programs. A number of companies in the biotechnology and pharmaceutical industries have suffered significant setbacks in clinical trials, even after promising results in

earlier preclinical studies or clinical trials. These setbacks have been caused by, among other things, preclinical ~~42findings~~ **findings** made while clinical trials were underway and safety or efficacy observations made in clinical trials, including previously unreported adverse events. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful, and the results of clinical trials by other parties may not be indicative of the results in trials we may conduct. We have not previously submitted a BLA or any other marketing application to the FDA or similar filings to comparable foreign regulatory authorities. A BLA or other similar regulatory filing requesting approval to market a product candidate must include extensive preclinical and clinical data and supporting information to establish that the product candidate is safe, pure and potent for each desired indication. The BLA or other similar regulatory filing must also include significant information regarding the chemistry, manufacturing and controls for the product. The research, testing, manufacturing, labeling, approval, marketing, sale and distribution of biological products are subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries, and such regulations differ from country to country. We are not permitted to market our product candidates in the United States or in any foreign countries until they receive the requisite approval from the applicable regulatory authorities of such jurisdictions. The FDA or comparable foreign regulatory authorities can delay, limit or deny approval of our product candidates for many reasons, including: ● our inability to demonstrate to the satisfaction of the FDA or a comparable foreign regulatory authority that our product candidates are safe and effective for the requested indication; ● the FDA or a comparable foreign regulatory authority' s disagreement with our trial protocol or the interpretation of data from preclinical studies or clinical trials; ● our inability to demonstrate that the clinical and other benefits of our product candidates outweigh any safety or other perceived risks; ● the FDA or a comparable foreign regulatory authority' s requirement for additional preclinical studies or clinical trials; ● the FDA or a comparable foreign regulatory authority' s non-approval of the formulation, labeling, or specifications of our product candidates; ● the FDA or a comparable regulatory authority' s failure to approve our manufacturing processes and facilities or the manufacturing processes and facilities of third-party manufacturers upon which we rely; or ● potential for approval policies or regulations of the FDA or a comparable foreign regulatory authority to significantly change in a manner rendering our clinical data insufficient for approval. Even if we eventually complete clinical testing and receive approval from the FDA or comparable foreign regulatory authorities for any of our product candidates, the FDA or comparable foreign regulatory authorities may grant approval contingent on the performance of costly additional clinical trials which may be required after approval. The FDA ~~or~~ **39or** comparable foreign regulatory authorities also may approve any of our product candidates for a more limited indication or a narrower patient population than we originally requested, and the FDA or comparable foreign regulatory authorities may not approve any of our product candidates with the labeling that we believe is necessary or desirable for the successful commercialization of any such product candidates. Of the large number of biopharmaceutical products in development, only a small percentage successfully complete the FDA or other regulatory bodies' approval processes and are commercialized. Any delay in obtaining, or inability to obtain, applicable regulatory approval would delay or prevent commercialization of our product candidates and would materially harm our business. ~~43Even~~ **Even** if a current or future product candidate receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third- party payors and others in the medical community necessary for commercial success. If any current or future product candidate we develop receives marketing approval, whether as a single agent or in combination with other therapies, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third- party payors, and others in the medical community. For example, current approved immunotherapies, and other cancer treatments like chemotherapy and radiation therapy, are well established in the medical community, and doctors may continue to rely on these therapies. Our approach to targeting different components of the TME is novel and unproven. In addition, adverse events in clinical trials testing our product candidates or in clinical trials of others developing similar product candidates and the resulting publicity, as well as any other adverse events in the field of immuno- oncology that may occur in the future, could result in a decrease in demand for our current or future product candidates. If public perception is influenced by claims that the use of cancer immunotherapies is unsafe, whether related to our therapies or our competitors' products, our products may not be accepted by the general public or the medical community. Future adverse events in immuno-oncology or the biopharmaceutical industry could also result in greater governmental regulation, stricter labeling requirements and potential regulatory delays in the testing or approvals of our products. If our current and any future product candidates we develop do not achieve an adequate level of acceptance, we may not generate significant product revenues and we may not become profitable. The degree of market acceptance of our current and any future product candidates, if approved for commercial sale, will depend on a number of factors, including: ● efficacy and potential advantages compared to alternative treatments, including those that are not yet approved; ● the ability to offer our products, if approved, for sale at competitive prices; ● convenience and ease of administration compared to alternative treatments; ● the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies; ● the strength of marketing, sales and distribution support; ● the ability to obtain sufficient third- party coverage and adequate reimbursement, including with respect to the use of the approved product as a combination therapy; ● the regulatory approval and adoption of a companion or complementary diagnostic, if needed or advisable; and ● the prevalence and severity of any side effects. The market opportunities for any current or future product candidate we develop, if approved, may be limited to those patients who are ineligible for established therapies or for whom prior therapies have failed, and may be small. Any revenue we are able to generate in the future from product sales will be dependent, in part, upon the size of the market in the United States and any other jurisdiction for which we gain regulatory approval and have commercial ~~rights~~ **40rights** . 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, even if approved. Cancer therapies are sometimes characterized as first- line, second- line or third- line, and the FDA often approves new therapies initially only for third- line use. When cancer is detected early enough, first- line therapy, usually chemotherapy, hormone therapy, surgery, radiation therapy or a combination of these, is sometimes adequate to cure the cancer or prolong life without a

cure. Second- and third- line therapies are administered to patients when prior therapy is not effective. We may initially seek approval for ~~NC410,~~ LNCB74 and any other product candidates we develop as second or third- line therapies. If we do so, for those products that prove to be sufficiently beneficial, if any, we would expect potentially to seek approval as a first- line therapy, but there is no guarantee that any product candidate we develop, even ~~44if~~ **if** approved, would be approved for first-line therapy, and, prior to any such approvals, we may have to conduct additional clinical trials. The number of patients who have the types of cancer we are targeting may turn out to be lower than expected. Additionally, the potentially addressable patient population for our current or future product candidates may be limited, if and when approved. Even if we obtain significant market share for any product candidate, if and when approved, if the potential target populations are small, we may never achieve profitability without obtaining marketing approval for additional indications, including to be used as first- or second- line therapy. We ~~are~~ **may** ~~studying~~ --- **study** ~~NC410~~ **LNCB74** in combination with other therapies and ~~may develop LNCB74 and~~ future product candidates in combination with other therapies, which exposes us to additional regulatory risks. We ~~are studying NC410 in combination with pembrolizumab and~~ may develop LNCB74 and future product candidates in combination with one or more currently approved cancer therapies ~~. In addition, we are supplying NC318 drug product to Yale in support of Yale' s IIT study of NC318 in combination with pembrolizumab~~. These combinations have not been tested before and may, among other things, fail to demonstrate synergistic activity, may fail to achieve superior outcomes relative to the use of single agents or other combination therapies, or may fail to demonstrate sufficient safety or efficacy traits in clinical trials to enable us to complete those clinical trials or obtain marketing approval for the combination therapy. In addition, we did not develop or obtain regulatory approval for, and we do not manufacture or sell, any of these approved therapeutics. Therefore, even if any product candidate we develop were to receive marketing approval or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risk that the FDA or comparable foreign regulatory authorities could revoke approval of the therapy used in combination with our product candidate or that safety, efficacy, manufacturing or supply issues could arise with these existing therapies. This could result in our own products being removed from the market or being less successful commercially. Combination therapies are commonly used for the treatment of cancer, and we would be subject to similar risks if we develop any of our product candidates for use in combination with other drugs or for indications other than cancer. We may also evaluate ~~NC410,~~ LNCB74 or any future product candidate in combination with one or more other cancer therapies that have not yet been approved for marketing by the FDA or comparable foreign regulatory authorities. We will not be able to market and sell ~~NC410,~~ LNCB74 or any product candidate we develop in combination with any such unapproved cancer therapies that do not ultimately obtain marketing approval. If the FDA or comparable foreign regulatory authorities do not approve these other biological products or revoke their approval of, or if safety, efficacy, manufacturing or supply issues arise with, the biologics we choose to evaluate in combination with ~~NC410,~~ LNCB74 or any product candidate we develop, we may be unable to obtain approval of or market any such product candidate. Even if we receive marketing approval of a product candidate, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense. If we fail to comply or experience unanticipated problems with our products, we may be subject to administrative and judicial enforcement, including monetary penalties, for non- compliance and our approved products, if any, could be deemed misbranded or adulterated and prohibited from continued distribution. Any marketing approvals that we receive for any current or future product candidate may be subject to limitations on the approved indicated uses for which the product may be marketed or the conditions of approval or contain requirements for potentially costly post-market testing and surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require implementation of a REMS as a condition of approval of any product candidate, ~~which~~ **41which** could include 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 and deviation reporting, storage, advertising, promotion, import and export and record keeping for the 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 cGMP and cGCP, for any clinical trials that we may conduct post- approval. Later discovery of previously unknown problems with any approved candidate, including adverse events of unanticipated severity or ~~45frequency~~ -- **frequency**, or with our or our third- party manufacturers' manufacturing processes or facilities, or failure to comply with regulatory requirements, may result in, among other things: ● suspension of, or imposition of restrictions on, the marketing or manufacturing of the product, withdrawal of the product from the market, or product recalls; ● Warning Letters or Untitled Letters, or holds on clinical trials; ● refusal by the FDA to approve pending applications or supplements to approved applications we file, or suspension or revocation of approved biologics licenses; ● product seizure or detention, monetary penalties, refusal to permit the import or export of the product, or placement on Import Alert; and ● permanent injunctions and consent decrees including the imposition of civil or criminal penalties. Given the nature of biologics manufacturing, there is a risk of contamination. Any contamination could materially adversely affect our ability to produce product candidates on schedule and could, therefore, harm our results of operations and cause reputational damage. Some of the raw materials and other components required in our manufacturing process are derived from biologic sources. Such raw materials are difficult to procure and may be subject to contamination or recall. A material shortage, contamination, recall or restriction on the use of biologically derived substances in manufacturing our product or product candidates could adversely impact or disrupt the commercial manufacturing or the production of clinical material, which could materially and adversely affect our development and commercialization timelines and our business, financial condition, results of operations and prospects and could adversely affect our ability to meet our supply obligations. Moreover, the FDA strictly regulates the promotional claims that may be made about drug and biological products. An approved product may not be promoted for uses that are not approved by the FDA as reflected in the product' s approved labeling, or off- label uses. The

FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off- label uses. The FDA has issued guidance on the factors that it will consider in determining whether a firm' s product communication is consistent with the FDA- required labeling for that product, and those factors contain complexity and potential for overlap and misinterpretation. A company that is found to have improperly promoted off- label uses of their products may be subject to significant civil, criminal and administrative penalties. The FDA and other regulatory authorities' policies may change, and additional government regulations may be enacted, that could prevent, limit or delay marketing approval of a product. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, and we may not achieve or sustain profitability. Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenue from our products. If regulatory sanctions are applied or if regulatory approval is withdrawn, the value of our company and our operating results will be adversely affected. ~~In~~ **42In** addition, 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. Obtaining and maintaining marketing approval of our current and future product candidates in one jurisdiction does not mean that we will be successful in obtaining and maintaining marketing approval of our current and future product candidates in other jurisdictions. Obtaining and maintaining marketing approval of our current and future product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain marketing approval in any other jurisdiction, while a failure ~~46or~~ **or** delay in obtaining marketing approval in one jurisdiction may have a negative effect on the marketing 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 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 marketing 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 or fail to receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed. We depend on data and our information technology systems, and any failure of these systems could harm our business. Security breaches, loss of data, and other disruptions could compromise sensitive information related to our business or prevent us from accessing critical information and expose us to liability, which could adversely affect our business, results of operations and financial condition. We collect and maintain information in digital form that is necessary to conduct our business, and we are dependent on our information technology systems and those of third parties to operate our business. In the ordinary course of our business, we collect, store and transmit large amounts of confidential information, including intellectual property, proprietary business information, personal information, protected health information and data to comply with cGMP and data integrity requirements. It is critical that we do so in a secure manner to maintain data security and data integrity of such information. We have established physical, electronic and organizational measures to safeguard and secure our systems to prevent a data compromise. We have also outsourced elements of our information technology infrastructure, and as a result a number of third- party vendors may or could have access to our confidential information. If we or our vendors fail to comply with applicable data privacy laws, or if the legal mechanisms we or our vendors rely upon for the transfer of personal data are ever deemed inadequate, or if we or our vendors experience a data breach resulting in exposure of personal data subject to the applicable laws, we could be subject to government enforcement actions and significant penalties against us, criminal and civil liability for us and our officers and directors, private litigation or adverse publicity. The OCR, pursuant to legislation passed in 2021, recently issued guidance on recognized security practices for covered entities and business associates, the OCR indicated that recognized security practices will not be an aggravating factor in OCR investigations, but that implementation of recognized security practices strengthen an organization' s cybersecurity and regulatory posture, as well as possibly lessening enforcement penalties in a potential regulatory enforcement. Our internal information technology systems and infrastructure, and those of our current and any future collaborators, contractors and consultants and other third parties on which we rely, are vulnerable to damage from computer viruses, malware, natural disasters, terrorism, war, telecommunication and electrical failures, cyber- attacks or cyber- intrusions, phishing, persons inside our organization or persons with access to systems inside our organization. We and our third ~~-~~ party service providers regularly defend against, respond to and mitigate risks from data security incidents. The risk of a security breach or disruption or data loss, including by computer hackers, foreign governments and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. In addition, the prevalent use of mobile devices that access confidential information ~~increases~~ **43increases** the risk of data security breaches, which could lead to the loss of confidential information or other intellectual property. The costs to us to mitigate network security problems, bugs, viruses, worms, malicious software programs, ransomware and security vulnerabilities could be significant, and while we have implemented security measures to protect our data security and

information technology systems, our efforts to address these problems may not be successful, and these problems could result in unexpected interruptions, delays, cessation of service and other harm to our business and our competitive position. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our product development programs. For example, the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on third parties to conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business. Moreover, if a computer ~~47security~~ -- **security** breach affects our systems or results in the unauthorized release of personally identifiable information, our reputation could be materially damaged. In addition, such a breach may require notification to governmental agencies, the media or individuals pursuant to various federal and state privacy and security laws, if applicable, including HIPAA and its implementing regulations, as well as regulations promulgated by the Federal Trade Commission and state breach notification laws. We would also be exposed to a risk of loss or litigation and potential liability, which could materially adversely affect our business, results of operations and financial condition. We may need to expend significant resources and make significant capital investment to protect against security breaches or to mitigate the impact of any such breaches. The successful commercialization of our product candidates will depend in part on the extent to which third-party payors, including governmental authorities and private health insurers, provide coverage and adequate reimbursement levels, as well as implement pricing policies favorable for our product candidates. Failure to obtain or maintain coverage and adequate reimbursement for our product candidates, if approved, could limit our ability to market those products and decrease our ability to generate revenue. The availability of coverage and adequacy of reimbursement by third- party payors, including managed care plans, governmental healthcare programs, such as Medicare and Medicaid and private health insurers is essential for most patients to be able to afford medical services and pharmaceutical products such as our product candidates that **may** receive FDA approval. Our ability to achieve acceptable levels of coverage and reimbursement for our products or procedures using our products by third- party payors will have ~~an effect~~ **affect** ~~on~~ our ability to successfully commercialize our product candidates. Obtaining coverage and adequate reimbursement for our products may be particularly difficult because of the higher prices often associated with drugs administered under the supervision of a physician. Separate reimbursement for the product itself or the treatment or procedure in which our product is used may not be available. A decision by a third- party payor not to cover or not to separately reimburse for our products or procedures using our products could reduce physician utilization of our products once approved. Assuming there is coverage for our product candidates, or procedures using our product candidates by a third- party payor, the resulting reimbursement payment rates may not be adequate or may require co- payments that patients find unacceptably high. We cannot be sure that coverage and reimbursement in the United States, the European Union or elsewhere will be available for our current or future product candidates, or for any procedures using such product candidates, and any reimbursement that may become available may not be adequate or may be decreased or eliminated in the future. Our ability to successfully commercialize any product candidate, whether as a single agent or combination therapy, will also depend in part on the extent to which coverage and reimbursement for these product candidates and related treatments will be available from third- party payors. Third- party payors decide which medications they will pay for and establish reimbursement levels. It is difficult to predict at this time what government authorities and third- party payors will decide with respect to coverage and reimbursement for our current and future product candidates. In addition, third- party payors are increasingly challenging prices charged for pharmaceutical and biological products and services, and many third- party payors may refuse to provide coverage and reimbursement for particular drugs or biologics when an equivalent generic drug, biosimilar or a less expensive therapy is available. It is possible that a third- party payor may consider our product candidates as substitutable and only offer to reimburse patients for the less expensive product. Even if we show improved efficacy or improved convenience of administration with our product candidates, pricing of existing third- party therapeutics may limit the amount we will be able to charge for our product candidates. These third- party payors may deny or revoke the reimbursement status of our product candidates, if approved, or establish prices for our product candidates at levels that are too low to enable us to realize an appropriate return on our investment. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our product candidates and may not be able to obtain a satisfactory financial return on our product candidates. ~~There~~ **44There** is significant uncertainty related to the insurance coverage and reimbursement of newly ~~-~~approved products, especially novel products like our therapies. To date, no regulatory authority has granted approval for ~~an immunomedicine targeting the LAIR pathway or~~ an ADC targeting B7- H4. The Medicare and Medicaid programs are increasingly used as models in the United States for how private third- party payors and other governmental payors develop their coverage and reimbursement policies for drugs and biologics. Some third- party payors may require pre- approval of coverage for new or innovative devices or drug therapies before they will reimburse healthcare providers who use such therapies. Moreover, eligibility for reimbursement does not imply that any drug will be reimbursed in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. We cannot predict at this time what third- party payors will decide with respect to the coverage and reimbursement for our product candidates. ~~48No~~ **No** uniform policy for coverage and reimbursement for products exist among third- party payors in the United States. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time- consuming and costly process that may require us to provide scientific and clinical support for the use of our product candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Furthermore, rules and regulations regarding reimbursement can change, in some cases on short notice ~~, and we believe that changes in these rules and regulations are likely~~ . Additionally, if we or our collaborators develop companion diagnostic tests for use with our product candidates, we, or our collaborators, will be required to obtain coverage and reimbursement for these tests separate and apart from the coverage and reimbursement we seek for our product candidates, once

approved. While we and our collaborators have not yet developed any companion diagnostic test for our product candidates, if we or our collaborators do, there is significant uncertainty regarding the ability to obtain coverage and adequate reimbursement for the same reasons applicable to our product candidates. Moreover, a primary trend in the healthcare industry in the United States and elsewhere is cost containment. Government authorities and third- party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, the third- party payors who reimburse patients or healthcare providers, such as government and private insurance plans, are requiring that drug companies provide them with predetermined discounts from list prices and are seeking to reduce the prices charged or the amounts reimbursed for medical products. We cannot be sure that coverage and reimbursement will be available for any drug that we commercialize and, if coverage and reimbursement are available, we cannot be sure as to the level of reimbursement. Reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval. We expect to experience pricing pressures in connection with the sale of our product candidates due to the trend toward managed health care, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and biologics and surgical procedures and other treatments, has become intense. As a result, increasingly high barriers are being erected to the entry of new products. Enacted healthcare legislation, changes in healthcare law and implementation of regulations, as well as changes in healthcare policy, may increase the difficulty and cost for us to commercialize our product candidates, may impact our business in ways that we cannot currently predict, could affect the prices we may set, and could have a material adverse effect on our business and financial condition. In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. 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, the ACA substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacted the U. S. pharmaceutical industry. The ACA, among other things, subjects biologics to potential competition by lower- cost biosimilars, addresses a methodology by which rebates owed by manufacturers under the MDRP are calculated for drugs that are inhaled, infused, instilled, implanted or injected, increases the minimum Medicaid rebates owed by manufacturers under the MDRP and extends the rebate program to individuals enrolled in Medicaid managed care organizations, and establishes annual fees and taxes on manufacturers of certain branded prescription drugs. The ACA and certain of its provisions have been subject to judicial challenges as well as legislative and regulatory efforts to repeal or replace them or to alter their interpretation or implementation. For example, Congress has considered ~~legislation~~ **45legislation** that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, bills affecting the implementation of certain taxes under the ACA have been signed into law. The Tax Act included a provision that repealed the tax- based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the " individual mandate. " Also, in 2018, CMS issued final rules permitting further collections and payments to and from certain ACA qualified health plans and health insurance issuers under the ACA risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. The Further Consolidated Appropriations Act of 2020 fully repealed the ACA' s " Cadillac Tax " on certain high ~~-~~ cost employer- sponsored insurance plans and, effective in 2021, the annual fee imposed on certain health insurance providers based on market share. On March 11, 2021, Congress enacted the American Rescue Plan Act of 2021, which included among its ~~49provisions~~ -- **provisions** a sunset of the ACA' s cap on pharmaceutical manufacturers' rebate liability under the Medicaid Drug Rebate Program. Under the ACA, manufacturers' rebate liability was capped at 100 % of the average manufacturer price for a covered outpatient drug. ~~Effective~~ **However, as of** January 1, 2024, manufacturers' MDRP rebate liability ~~will~~ **is** no longer ~~be~~ capped, potentially resulting in a manufacturer paying more in MDRP rebates than it receives on the sale of certain covered outpatient drugs. The American Rescue Plan Act also temporarily increased premium tax credit assistance for individuals eligible for subsidies under the ACA for 2021 and 2022 and removed the 400 % federal poverty level limit that otherwise applies for purposes of eligibility to receive premium tax credits. **The IRA extended this increased tax credit assistance and removal of the 400 % federal poverty limit through 2025.** In the future, there may be additional challenges and / or amendments to the ACA. It remains to be seen precisely what any new legislation will provide, when or if it will be enacted, and what impact it will have on the availability and cost of healthcare items and services, including drug products. On June 17, 2021, the U. S Supreme Court dismissed a legal challenge to the law brought by several states arguing that, without the individual mandate, the entire ACA was unconstitutional. The Supreme Court dismissed the lawsuit without ruling on the merits of the states' constitutionality arguments. It is unclear how future litigation and ~~the~~ **any** healthcare reform measures of the ~~Biden~~ **Trump** administration will impact the ACA and our business. Other healthcare- related legislative and regulatory initiatives and reforms have been proposed and adopted in the United States since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for automatic spending reductions under certain circumstances. In conjunction with the operation of subsequently enacted law, this has resulted in aggregate reductions of Medicare payments to providers of, on average, 2 % per fiscal year, which will remain in effect through the first ~~seven~~ **eight** months of the FY 2032 sequestration order, with the exception of a temporary suspension from May 1, 2020 through March 31, 2022 and a subsequent reduction to 1 % from April 1, 2022 until June 30, 2022 due to the COVID- 19 pandemic, unless Congress takes additional action. The American Taxpayer Relief Act of 2012, which was signed into law in January 2013, among other things, further reduced Medicare payments to several types of providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. For example, beginning in 2018, CMS has maintained a reduced rate of payment under the Medicare outpatient prospective payment system and ambulatory surgical center

payment system for certain separately payable drugs or biologics acquired under the 340B Drug Pricing Program. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for any product candidate we develop or complementary or companion diagnostics or additional pricing pressures. CMS may develop new payment and delivery models, such as bundled payment models. In addition, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several U. S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under government payor programs, and review the relationship between pricing and manufacturer patient programs; and reform government program reimbursement methodologies for drugs. For example, **on February 14** ~~included in the Consolidated Appropriations Act~~, ~~2021~~ **2023** ~~were several~~ **, HHS issued a report that, among other things, selected three potential** drug ~~price~~ **affordability and accessibility models to be tested by the CMS Innovation Center. Specifically, the** ~~reporting~~ **report addressed: (1)** ~~and transparency measures, such as~~ a ~~new requirement~~ **model that would allow Part D Sponsors to establish a " high- value drug list " setting the maximum co- payment amount** for certain **common generic drugs at $ 2; (2) a** ~~Medicare~~ **Medicaid** ~~plans to develop tools to display~~ **- focused model that would establish a partnership between CMS, manufacturers, and state Medicaid agencies that would result in multi- state outcomes- based agreements or certain cell and gene therapy drugs; and (3) a model that would adjust** Medicare Part ~~D prescription~~ **B payment amounts for Accelerated Approval Program** ~~drug~~ **drugs** ~~benefit information in real time and for group and health insurance issuers~~ to **advance** ~~report information on pharmacy benefit and drug costs to~~ the ~~Secretaries~~ **developments** of ~~the~~ **novel** ~~Departments~~ -- **treatments** ~~of Health and Human Services, Labor and the Treasury~~. Additionally, ~~in~~ **46in** August 2022, **former** President Biden signed into law the ~~Inflation Reduction Act of 2022 (the "~~ IRA ~~")~~, which implements substantial changes to the Medicare program, including drug pricing reforms and the creation of new Medicare inflation rebates. Namely, the IRA imposes inflation rebates on drug manufacturers for products reimbursed under Medicare Parts B and D if the prices of those products increase faster than inflation; implements changes to the Medicare Part D benefit that, beginning in 2025, ~~will~~ cap beneficiary annual out- of- pocket spending at $ 2, 000, while imposing new discount obligations for pharmaceutical manufacturers; and, beginning in 2026, establishes a " maximum fair price " for a fixed number of high expenditure pharmaceutical and biological products covered under Medicare Parts B and D following a price negotiation process with CMS. CMS has also taken steps to implement the IRA, including: ~~on June 30~~ **releasing the negotiated maximum prices** , **which will be effective in** ~~2023~~ **2026** , **for** ~~issuing guidance detailing the requirements and parameters of~~ the first ~~round of price negotiations, to take place during 2023 and 2024, for products subject to the " maximum fair price " provision that would become effective in 2026; on August 29, 2023, releasing the initial list of~~ ten drugs **that were** subject to ~~price~~ **the IRA' s** ~~negotiations~~ **negotiation process** ~~; on November 17, 2023~~, releasing **quarterly** ~~guidance outlining the methodology for identifying certain manufacturers eligible to participate in a phase- in period where discounts on applicable products will be lower than those required by the Medicare Part D Manufacturer Discount Program; and on December 14, 2023, releasing a list~~ **lists** of ~~48~~ Medicare Part B products that ~~50had an~~ **are subject to** adjusted coinsurance ~~rate~~ **rates** based on the inflationary rebate provisions of the IRA ~~for the time period of January 1~~, **and announcing a list of fifteen additional drugs that will be subject to price negotiations during** ~~2024~~ **2025** ~~to March 31, 2024~~. While it remains to be seen how the drug pricing provisions imposed by the IRA will affect the broader pharmaceutical industry, several pharmaceutical manufacturers and other industry stakeholders have challenged the law, including through lawsuits brought against **HHS** ~~the U. S. Department of Health and Human Services~~, the Secretary of **HHS** ~~the U. S. Department of Health and Human Services~~, CMS, and the CMS Administrator challenging the constitutionality and administrative implementation of the IRA' s drug price negotiation provisions. In addition ~~, on February 2, 2022, the Biden administration signaled its continued commitment to the Cancer Moonshot initiative, which was initially launched in 2016. In its announcement, the administration noted that its new goals under the initiative include addressing inequities in order to ensure broader access to cutting- edge cancer therapeutics and investing in a robust pipeline for new treatments. In alignment with President Biden' s Cancer Moonshot initiative~~, on June 27, 2023, the Center for Medicare Innovation at CMS announced a new model, the Enhancing Oncology Model, that is designed to make high- quality cancer care more affordable to both patients and Medicare. **While it is uncertain how** ~~On October 14, 2022 President Biden issued an Executive Order on Lowering Prescription Drug Costs for Americans, which instructed the~~ **these models may be affected** ~~Secretary of the Department of Health and Human Services to consider whether to select for testing~~ by the **recent change** ~~CMS Innovation Center new health care payment and delivery models that would lower drug costs and promote access to innovative drug therapies for beneficiaries enrolled~~ in **presidential administration** ~~the Medicare and Medicaid programs. On February 14~~, **we** ~~2023, the Department of Health and Human Services issued a report in response to the October 14, 2022 Executive Order, which, among other things, selects three potential drug affordability and accessibility models to be tested by the CMS Innovation Center. Specifically, the report addresses: (1) a model that would allow Part D Sponsors to establish a " high- value drug list " setting the maximum out- of- pocket costs for certain common generic drugs at $ 2 per drug per month; (2) a Medicaid- focused model that would establish a partnership between CMS, manufacturers, and state Medicaid agencies that would result in multi- state outcomes- based agreements or certain cell and gene therapy drugs; and (3) a model that would adjust Medicare Part B payment amounts for Accelerated Approval Program drugs to advance the developments of novel treatments. We~~ expect that ~~additional U. S. federal healthcare reform measures~~ **regulatory initiatives intended to address the cost of prescription pharmaceuticals and biological products** will **continue to** be ~~adopted~~ **introduced** in the future ~~, any of which could limit the extent to which the U. S. federal government covers particular healthcare products and services and could limit the amounts that the U. S. federal government will pay for healthcare products and services. This could result in reduced demand for our product candidates or additional pricing pressures~~. Individual states in the United States have also increasingly passed legislation and implemented regulations

designed to control pharmaceutical and biological product pricing, including price or patient reimbursement limitations, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third- party payors or other restrictions on coverage or access could harm our business, results of operations, financial condition and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. **Some states have also established prescription drug affordability boards that are tasked with identifying certain high- cost prescription products that may pose affordability challenges for consumers and payers, conducting cost reviews on such products, and, in some circumstances, imposing upper payment limits on such products.** This could reduce the ultimate demand for our product candidates that we successfully commercialize or put pressure on our product pricing. Additionally, in May 2018, the Right to Try Act was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase 1 clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a pharmaceutical manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action in the United States. If we or any third parties we may engage are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or such third parties are not able to maintain regulatory compliance, our product candidates may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability. **The pharmaceutical industry is subject to extensive regulatory obligations and policies that may be subject to significant and abrupt change, including due to judicial challenges, election cycles, and resulting regulatory updates and changes in policy priorities. On June 28, 2024, the U. S. Supreme Court issued an opinion holding that courts reviewing agency action pursuant to the APA " must exercise their independent judgment " and " may not defer to an agency interpretation of the law simply because a statute is ambiguous. " The decision will have a significant impact on how lower courts evaluate challenges to agency interpretations of law, including those by HHS, CMS, FDA and other agencies with significant oversight of the biopharmaceutical industry. The new framework is likely to increase both the frequency of such challenges and their odds of success by eliminating one way in which the government previously prevailed in such cases. As a result, significant regulatory policies will be subject to increased litigation and judicial scrutiny. 47In addition, federal agency priorities, leadership, policies, rulemaking, communications, spending, and staffing may be significantly impacted by election cycles, including, for example, the current presidential administration' s commitment to significantly reduce government spending through cuts to federal healthcare programs and reductions in the workforces of key government agencies, such as HHS, FDA, and CMS. Efforts by the current administration to limit federal agency budgets or personnel may lead to slower response times and longer review periods, potentially affecting our ability to progress development of our product candidates or obtain regulatory approval for our product candidates. Any resulting changes in regulation may result in unexpected delays, increased costs, or other negative impacts on our business that are difficult to predict.** Our relationships with customers, third- party payors and others may be subject to applicable anti- kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, administrative burdens and diminished profits and future earnings. Healthcare providers, physicians and third- party payors in the United States and elsewhere will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our ~~51current~~ **current** and future arrangements with healthcare providers, third- party payors, customers, and others may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations, which may constrain the business or financial arrangements and relationships through which we research, as well as sell, market and distribute any products for which we obtain marketing approval. The applicable federal and state healthcare laws and regulations that may affect our ability to operate include, but are not limited to, those described in " Business — Government Regulation — Healthcare Regulation. " Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available under such laws, it is possible that some of our business activities could be subject to challenge under one or more of such laws. The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform. Federal and state enforcement bodies continue to increase their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Ensuring that our business arrangements with third parties comply with applicable healthcare laws, as well as responding to investigations by government authorities, can be time and resource consuming and can divert management' s attention from the business. If our operations are found to be in violation of any of the laws described above or any other government regulations that apply to us, we may be subject to penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, possible exclusion from participation in federal and state funded healthcare programs, contractual damages and the curtailment or restricting of our operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non- compliance with these laws. Further, if the physicians or other providers or entities with whom we expect to do business are found not to be in compliance with applicable laws, they may be subject to criminal, civil and administrative sanctions, including exclusion from government funded healthcare programs. In addition, the approval and commercialization of any product candidate we develop outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws. All of these could harm our ability to operate our business and our financial results. We are subject to certain U. S. and foreign anti- corruption, anti- money laundering, export

control, sanctions and other trade laws and regulations. We can face serious consequences for violations. Among other matters, U. S. and foreign anti- corruption, anti- money laundering, export control, sanctions and other trade laws and regulations, which are collectively referred to as Trade Laws, prohibit companies and their employees, agents, clinical research organizations, legal counsel, accountants, consultants, contractors and other partners from engaging in certain prohibited activities, including transacting with certain foreign individuals or companies, operating in or cooperation with entities from certain foreign jurisdictions or with foreign government entities, or authorizing, promising, offering, providing, soliciting, or receiving directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. Violations of Trade Laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm and other consequences. ~~Our~~ **48Our** business is heavily regulated and therefore involves significant interaction with public officials. We have direct or indirect interactions with officials and employees of government agencies or government- affiliated hospitals, universities and other organizations. We also expect our non- U. S. activities to increase in time. Additionally, in many other countries, the health care providers who prescribe pharmaceuticals are employed by their government, and the purchasers of pharmaceuticals are government entities; therefore, our dealings with these prescribers and purchasers are subject to regulation under the U. S. Foreign Corrupt Practices Act of 1977, as amended, or " FCPA ". We plan to engage third parties for clinical trials or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals and we can be held liable for the corrupt or other illegal activities of our personnel, agents, or partners, even if we do not explicitly authorize or have prior knowledge of such activities. In particular, our operations will be subject to FCPA, which prohibits, among other things, U. S. companies and their employees and agents from authorizing, promising, offering, or providing, directly or indirectly, corrupt or improper payments or anything else of value to foreign government officials, employees of public international organizations and foreign government- owned or affiliated entities, candidates for foreign political office, and foreign political parties or officials thereof. Recently, the SEC and Department of Justice have increased their FCPA enforcement activities with respect to biotechnology and pharmaceutical companies. There is no certainty that all of our employees, agents, suppliers, manufacturers, contractors, or collaborators, or those of our affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws. ~~52Violations~~ -- **Violations** of these laws and regulations could result in fines, criminal sanctions against us, our officers, or our employees, the closing down of facilities, including those of our suppliers and manufacturers, requirements to obtain export licenses, cessation of business activities in sanctioned countries, implementation of compliance programs and prohibitions on the conduct of our business. Any such violations could also result in prohibitions on our ability to offer our products in one or more countries as well as difficulties in manufacturing or continuing to develop our products, and could materially damage our reputation, our brand, our international expansion efforts, our ability to attract and retain employees and our business, prospects, operating results and financial condition. We collaborate with research institutions, strategic business partners, and contractors, including contract manufacturing organizations, that are located within, and exist under the laws of foreign countries. As the Trade Laws evolve and change, it may restrict our ability to continue to collaborate with our preferred partners, institutions and contractors abroad. If Trade Laws are adopted that impact our foreign collaborators, such laws could materially negatively impact our ability to develop, manufacture and obtain marketing approval for our product candidates. For example, the BIOSECURE Act (H. R. 7085) legislation introduced in the United States Congress on January 25, 2024, if enacted, could restrict the ability of U. S. pharmaceutical companies to collaborate with certain Chinese entities without losing the ability to contract with the U. S. government. Such could harm our ability to operate our business and our financial results. If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business. We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties. Although we maintain workers' compensation insurance to cover us for costs and expenses, we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological or hazardous materials. Risks Related to ManufacturingGiven our limited operating history, our manufacturing experience as an organization and with our manufacturing facility is limited **, particularly following a recent restructuring that paused manufacturing operations** . Manufacturing is a critical component of our approach to developing therapies and we have invested significantly in our manufacturing facility. ~~We had~~ **Previously we** manufactured our product candidates for preclinical and clinical trials, but ~~announced~~ **49announced in March 2024** as part of our restructuring, ~~paused~~ the **pausing of** manufacturing operations as we believe ample clinical mAb supply has been produced, including the LNCB74 mAb intermediate, to supply programs in the near term. Manufacturing drugs for clinical trials and for commercial sale is subject to oversight by the FDA to ensure compliance with cGMP and by other regulatory authorities under other laws, regulations and standards. We cannot assure you that we can successfully manufacture our products in compliance with cGMP and with any other applicable laws, regulations and standards in sufficient quantities for clinical trials or for commercial sale, or in a timely or economical manner. Our manufacturing facility requires specialized personnel and is expensive to operate and maintain. Validation is an ongoing process that must be maintained to allow us to manufacture under cGMP guidelines. We cannot guarantee that our facility will remain in compliance with cGMP. Manufacturing pharmaceutical products is a highly complex process in which a variety of difficulties may arise

from time to time. We are currently the sole manufacturer of ~~NC410, and the sole manufacturer of~~ antibody materials for ~~53LNCB74 --~~ **LNCB74** , and if anything were to interfere with our continuing manufacturing operations in our facility, **once we recommence our manufacturing operations, such interference** it could materially adversely affect our business and financial condition. If we fail to secure sufficient manufacturing capacity with a suitable third party, or fail to manufacture our product candidates economically or on reasonable scale or volumes, or in accordance with cGMP, our development programs and commercialization of any approved products will be materially adversely affected. This may result in delays in commencing or continuing our clinical trials for ~~NC410 and~~ LNCB74. Any such delays could materially adversely affect our business and financial condition. **Additionally, if and when we decide to recommence manufacturing operations, we may undergo a ramp- up period that could cause a temporary shortage of materials for our clinical trials and other needs.** We may be unable to successfully scale- up manufacturing of our product candidates in sufficient quality and quantity, which would delay or prevent us from developing and, if approved, commercializing our product candidates. In order to conduct clinical trials of our product candidates, we will need to manufacture them in sufficient quantities. ~~Currently~~ **Previously** , **we manufactured** our product candidates ~~are manufactured~~ in small quantities for use in various preclinical studies and our ongoing ~~Phase 1 / 2 clinical trials of NC410 Combo and~~ Phase 1 clinical trial **LNCB74. However, in March 2024, as part** of ~~NC525~~ **a broader restructuring, we paused our manufacturing operations** . If one or more of our product candidates progress to late- stage development, we will need to scale up our internal capabilities or otherwise source suitable third party manufacturing capabilities, which may require additional significant expenses in the further expansion or construction of manufacturing facilities and increases in personnel in order to manufacture product candidates in sufficient quantities. We cannot assure you that we will be able to successfully manufacture product candidates at a larger scale in a timely or economical manner, or at all. If we are unable to successfully scale our internal and / or external manufacturing capacity, the development, testing and clinical trials of our current or future product candidates may be delayed or infeasible, and regulatory approval or commercial launch of any resulting product may be delayed or not obtained, which could significantly harm our business. The loss of our third- party manufacturing partners or our, or our partners', failure to comply with applicable regulatory requirements or to supply sufficient quantities at acceptable quality levels or prices, or at all, would materially and adversely affect our business. Although we have manufactured our product candidates ~~NC410 and NC525~~ for preclinical and clinical trials, certain elements of manufacturing, including Master Cell Bank manufacturing and fill- finish services, take place at qualified third- party contract manufacturing organizations, or CMOs. Further, we are working with CMOs to manufacture drug substance for LNCB74 in addition to providing Master Cell Bank manufacturing and fill- finish services. If approved, commercial supply of ~~NC410,~~ LNCB74 and any future product candidates may be manufactured at a CMO or CMOs. The facilities used by our CMOs to manufacture our product candidates are subject to various regulatory requirements and may be subject to the inspection of the FDA or other regulatory authorities. We do not control the manufacturing process at our CMOs and are completely dependent on them for compliance with current regulatory requirements. If we or our CMOs cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or comparable regulatory authorities in foreign jurisdictions, we may not be able to rely on their manufacturing facilities for manufacturing elements of our product candidates. In addition, we have limited control over the ability of our CMOs to maintain adequate quality control, quality assurance and qualified personnel. If ~~the~~ **50the** FDA or a comparable foreign regulatory authority finds our facilities or those of our CMOs inadequate for manufacturing our product candidates or if such facilities are subject to enforcement action in the future or are otherwise inadequate, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates. Further, any facilities located outside the United States that are used by our CMOs to manufacture our product candidates, including LNCB74, will likewise be subject to various regulatory requirements of the jurisdiction in which they are located and in addition be subject to Trade Laws and regulations of the United States that may restrict our ability to continue to utilize our preferred CMOs. For example, WuXi XDC, which is currently the only CDMO we currently use to conjugate our B7- H4 antibody and produce LNCB74 ADC drug product, is affiliated with WuXi AppTec. WuXi AppTec was identified as a United States national security threat in the proposed BIOSECURE Act, which if enacted, or if alternatively implemented through executive or administrative action, could restrict WuXi' s business in the United States or the ability of businesses in the United States to conduct business with WuXi. Moreover, if a foreign regulatory authority curtails operations at such foreign facilities of our CMOs, or if Trade Laws are adopted limiting our ability to use such ~~54CMO --~~ **CMO** facilities, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates. Additionally, our CMOs may experience manufacturing difficulties due to resource constraints or as a result of labor disputes or unstable political environments. If our CMOs were to encounter any of these difficulties, our ability to provide our product candidate to patients in clinical trials, or to provide product for the treatment of patients once approved, would be jeopardized. We are subject to multiple manufacturing risks, any of which could substantially increase our costs and limit supply of our product candidates. The process of manufacturing therapies, including our product candidates, is complex, time- consuming, highly regulated and subject to several risks, including: ● product loss during the manufacturing process, including loss caused by contamination, equipment failure or improper installation or operation of equipment, or operator error. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects and other supply disruptions. If microbial, viral or other contaminations are discovered in our products or in the manufacturing facilities in which our products are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination; ● the manufacturing facilities in which our products are made could be adversely affected by equipment failures, labor and raw material shortages, including due to restrictions on the movement of people or goods, natural disasters, public health emergencies, power failures, other business disruptions and numerous other factors; and ● any adverse developments affecting manufacturing operations for our products may result in shipment delays, inventory shortages, lot failures, product withdrawals

or recalls, or other interruptions in the supply of our products. We may also have to take inventory write- offs and incur other charges and expenses for products that fail to meet specifications, undertake costly remediation efforts or seek more costly manufacturing alternatives. We may also make changes to our manufacturing processes at various points during development, for a number of reasons, such as controlling costs, achieving scale, decreasing processing time, increasing manufacturing success rate or other reasons. Such changes carry the risk that they will not achieve their intended objectives, and any of these changes could cause our product candidates to perform differently and affect the results of our ongoing or future clinical trials. In some circumstances, changes in the manufacturing process may require us to perform ex vivo comparability studies and to collect additional data from patients prior to undertaking more advanced clinical trials. For instance, changes in our process during the course of clinical development may require us to show the comparability of the product used in earlier clinical phases or at earlier portions of a trial to the product used in later clinical phases or later portions of the trial. ~~We~~ **51We** depend on third- party suppliers for key materials used in our manufacturing processes, and the loss of these third- party suppliers or their inability to supply us with adequate materials, or rising prices due to inflation, could harm our business. We rely on third- party suppliers for certain materials and components required for the production of our product candidates. Our dependence on these third- party suppliers and the challenges we may face in obtaining adequate supplies of materials involve several risks, including limited control over pricing, availability, and quality and delivery schedules. As a small company, our negotiation leverage is limited, and we are likely to get lower priority than our competitors that are larger than we are. In addition, COVID- 19, the war in Russia and Ukraine, and resulting economic conditions have disrupted global supply chains, including pharmaceutical and medical supply chains. We cannot be certain that our suppliers will continue to provide us with the quantities of the raw materials that we require or satisfy our anticipated specifications and quality requirements whether due to our size, COVID- 19, or otherwise. Any supply interruption in limited or sole sourced raw materials could materially harm our ability to manufacture our product candidates until a new source of supply, if any, could be identified and qualified. We may be unable to find a sufficient alternative supply channel in a reasonable time or on commercially reasonable terms. Any performance failure on the part of our suppliers could delay the development and potential commercialization of our product candidates, including limiting supplies necessary ~~55for~~ -- **for** clinical trials and regulatory approvals, which would have a material adverse effect on our business. In addition, the current inflationary period may result in higher prices from our suppliers, which could materially increase our costs. Changes in methods of product candidate manufacturing or formulation may result in additional costs or delay. As product candidates proceed through preclinical studies to late- stage clinical trials towards potential approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the materials manufactured using altered processes. Such changes may also require additional testing, FDA notification or FDA approval. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates and jeopardize our ability to commence sales and generate revenue. Risks Related to Intellectual PropertyWe have filed patent applications for our product candidates, but no patent has yet issued from these applications. If we are unable to obtain and maintain patent protection for our product candidates, or if the scope of the patent protection obtained is not sufficiently broad or robust, our competitors could develop and commercialize products similar or identical to ours, and our ability to successfully commercialize our product candidates may be adversely affected. Our success depends, in large part, on our ability to obtain and maintain patent protection in the United States and other countries with respect to our product candidates. We and our licensors have sought, and intend to seek, to protect our proprietary position by filing patent applications in the United States and abroad related to our product candidates and technology that are important to our business. To date, only a limited number of patents have issued from our patent applications. The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has, in recent years, been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued that protect our technology or product candidates or that effectively prevent others from commercializing competitive technologies and product candidates. Because patent applications in the United States and most other countries are confidential for a period of time after filing, and some remain so until issued, we cannot be certain that we or our licensors were the first to file a patent application relating to any particular aspect of a product candidate. Furthermore, if third parties have filed such patent applications, we may challenge their ownership, for example in a derivation proceeding before the USPTO, to determine who has the right to the claimed subject matter in the applications. Similarly, if our patent applications are challenged in a derivation proceeding, the USPTO may hold that a third- party is entitled to certain patent ownership rights instead of us. We may then be forced to seek a license from the third party that may not be available on commercially favorable terms, or at all. The patent prosecution process is expensive, time- consuming and complex, and we may not be able to file, prosecute, maintain, enforce or license all necessary or desirable patent applications at a reasonable cost or in a timely ~~manner~~ **52manner** . It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Even if the patent applications we license or own do issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us or otherwise provide us with any competitive advantage. Our competitors or other third parties may be able to circumvent our patents by developing similar or alternative technologies or products that do not infringe our patents. We are party to a license agreement with Yale University under which we acquired rights to intellectual property related to certain of our product candidates. If we breach our obligations under this agreement, the agreement could be terminated, which would adversely affect our business and prospects. We are a party to a license agreement with Yale pursuant to which we in- license patents and technology for certain of

our product candidates. This license imposes various diligence, milestone payment, royalty, insurance and other obligations on us. If we fail to comply with these and other obligations or otherwise materially breach this license ~~56agreement --~~ **agreement** , Yale may have the right to terminate the license. If this agreement is terminated, we may not be able to develop, manufacture, market or sell the product candidates or products covered by the agreement, or we would have to negotiate a new or reinstated agreement, which may not be available to us on equally favorable terms, or at all. Our intellectual property agreements with third parties may be subject to disagreements over contract interpretation, which could narrow the scope of our rights to the relevant intellectual property or technology or increase our financial or other obligations to our licensors. Certain provisions in our intellectual property agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could affect the scope of our rights to the relevant intellectual property or technology or affect financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates. Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by government patent agencies, and our patent protection could be reduced or eliminated for non- compliance with these requirements. Periodic maintenance fees, renewal fees, annuity fees and various other government fees on patents or applications will be due to be paid to the USPTO and various government patent agencies outside of the United States over the lifetime of our licensed patents or applications and any patent rights we own or may own in the future. We rely, in part, on our outside counsel or our licensing partners to pay these fees due to the USPTO and to non- U. S. patent agencies. The USPTO and various non- U. S. government patent agencies require compliance with several procedural, documentary, fee payment and other similar provisions during the patent application process. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which non- compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market and this circumstance could have a material adverse effect on our business. We may not be able to protect our intellectual property rights throughout the world. Filing, prosecuting and enforcing patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States are and could remain 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 be less likely to be able to prevent third parties from infringing our patents in all countries outside the United States, or from selling or importing products that infringe our patents 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~~ **53strong** 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 countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our licensors is forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired and our business, financial condition, results of operations and prospects may be adversely affected. Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our product candidates. Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. Assuming that other requirements for patentability were met, prior to March 2013, in the United States, the first to invent ~~57the --~~ **the** claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. After March 2013, under the Leahy- Smith America Invents Act, or the " America Invents Act ", the United States transitioned to a first inventor to file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. The America Invents Act also included a number of significant changes that affected the way patent applications are prosecuted and also may affect patent litigation. These include allowing third- party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity or ownership of a patent by USPTO administered post- grant proceedings, including post- grant review, inter partes review and derivation proceedings. Additional changes in patent law could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects. In addition, the patent positions of companies in the development and commercialization of biologics and pharmaceuticals are particularly uncertain. Recent rulings from the U. S. Court of Appeals for the Federal Circuit and the U. S. Supreme Court have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. This combination of events has created uncertainty with respect to the validity and enforceability of patents. Depending on future actions by the U. S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our existing patent portfolio and our ability to protect and enforce our intellectual property in the future. We may become involved in lawsuits to protect or enforce our intellectual property, which could be expensive, time- consuming and unsuccessful. Competitors may infringe our patents or the patents of our licensors, or we may be required to defend against claims of infringement. Countering infringement or unauthorized use claims or defending against

claims of infringement can be expensive and time- consuming. Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future marketing, sales or distribution activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. In addition, 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, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of ~~competing~~ **54competing** 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 own, develop or license. Issued patents covering our product candidates could be found invalid or unenforceable if challenged in court. We may not be able to protect our trade secrets in court. If we or one of our licensing partners initiate legal proceedings against a third party to enforce any patent that is issued covering one of our product candidates, the defendant could counterclaim that the patent covering our product candidate is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, written description or non-enablement. In addition, patent ~~58validity~~ -- **validity** challenges may, under certain circumstances, be based upon non- statutory obviousness- type double patenting, which, if successful, could result in a finding that the claims are invalid for obviousness-type double patenting or the loss of patent term, including a patent term adjustment granted by the USPTO, if a terminal disclaimer is filed to obviate a finding of obviousness- type double patenting. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld information material to patentability from the USPTO, or made a misleading statement, during prosecution. Third parties also may raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re- examination, post grant review, inter partes review and equivalent proceedings in foreign jurisdictions. Such proceedings could result in the revocation or cancellation of or amendment to our patents in such a way that they no longer cover our product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. We cannot be certain that there is no invalidating prior art of which the patent examiner and we or our licensing partners were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we could lose part, and perhaps all, of the patent protection on one or more of our product candidates. Such a loss of patent protection could have a material adverse impact on our business. In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know- how that is not patentable or that we elect not to patent, processes for which patents are difficult to enforce and any other elements of our product candidate discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents, including portions of our FIND platform. However, trade secrets can be difficult to protect, and some courts inside and outside the United States are less willing or unwilling to protect trade secrets. Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business and financial condition. Our commercial success depends upon our ability and the ability of any collaborators to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing the proprietary rights and intellectual property of third parties. We cannot provide any assurances that third- party patents do not exist which might be enforced against our current manufacturing methods, product candidates or future methods or products, resulting in either an injunction prohibiting our manufacture or sales, or, with respect to our sales, an obligation on our part to pay royalties or other forms of compensation to third parties. The biotechnology and pharmaceutical industries are characterized by extensive and complex litigation regarding patents and other intellectual property rights. We may in the future become party to, or be threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our product candidates and technology, including post grant review and inter partes review before the USPTO. The risks of being involved in such litigation and proceedings may also increase as our product candidates approach commercialization and as we gain greater visibility as a public company. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future, regardless of their merit. There is a risk that third parties may choose to engage in litigation with us to enforce or to otherwise assert their patent rights against us. Even if we believe such claims are without merit, a court ~~of~~ **55of** competent jurisdiction could hold that these third- party patents are valid, enforceable and infringed, which could materially and adversely affect our ability to commercialize any of our product candidates or technologies covered by the asserted third- party patents. If we are found to infringe a third party' s valid and enforceable intellectual property rights, we could be required to obtain a license from such third party to continue developing, manufacturing and marketing our product candidates and technology. However, we may

not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non- exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments. We could be forced, including by court order, to cease developing, manufacturing and commercializing the infringing technology or product candidates. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent or other intellectual property right. A finding of infringement could prevent us from manufacturing and commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business, financial condition, results of operations and prospects. ~~59Others~~ -- **Others** may claim an ownership interest in our intellectual property and our product candidates, which could expose us to litigation and have a significant adverse effect on our prospects. While we are presently unaware of any claims or assertions by third parties with respect to our patents or other intellectual property, we cannot guarantee that a third party will not assert a claim or an interest in any of such patents or intellectual property. For example, a third party may claim an ownership interest in one or more of our, or our licensors', patents or other proprietary or intellectual property rights. A third party could bring legal actions against us to seek monetary damages or enjoin clinical testing, manufacturing or marketing of the affected product candidate or product. If we become involved in any litigation, it could consume a substantial portion of our resources and cause a significant diversion of effort by our technical and management personnel. If any such action is successful, in addition to any potential liability for damages, we could be required to obtain a license to continue to manufacture or market the affected product candidate or product, in which case we could be required to pay substantial royalties or grant cross- licenses to patents. We cannot, however, assure you that any such license would be available on acceptable terms, if at all. Ultimately, we could be prevented from commercializing a product, or forced to cease some aspect of our business operations as a result of claims of patent infringement or violation of other intellectual property rights. Further, the outcome of intellectual property litigation is subject to uncertainties that cannot be adequately quantified in advance, including the demeanor and credibility of witnesses and the identity of any adverse party. This is especially true in intellectual property cases, which may turn on the testimony of experts as to technical facts upon which experts may reasonably disagree. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations or prospects. If we are unable to protect the confidentiality of our proprietary information, the value of our technology and products could be adversely affected. Trade secrets and know- how can be difficult to protect. To maintain the confidentiality of trade secrets and proprietary information, we enter into confidentiality agreements with our employees, consultants, collaborators and others upon the commencement of their relationships with us. These agreements require that all confidential information developed by the individual or made known to the individual by us during the course of the individual' s relationship with us be kept confidential and not disclosed to third parties. Our agreements with employees and our personnel policies also provide that any inventions conceived by the individual in the course of rendering services to us shall be our exclusive property. However, we cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary technology and processes, and individuals with whom we have these agreements may not comply with their terms. Thus, despite such agreement, there can be no assurance that such inventions will not be assigned to third parties. In the event of unauthorized use or disclosure of our trade secrets or proprietary information, these agreements, even if obtained, may not provide meaningful protection, particularly for our trade secrets or other confidential information. To the extent that our employees, consultants or contractors use technology or know- how owned by third parties in their work for us, disputes may arise between us and those third parties as to the rights in related inventions. To the extent that an individual who is not obligated to assign rights in intellectual property to us is rightfully an inventor of intellectual property, we may need to obtain an assignment or a license to that intellectual property from that individual, or a third party or from that individual' s assignee. Such assignment or license may not be available on commercially reasonable terms or at all. We also seek to preserve the integrity and confidentiality of our trade secrets ~~by~~ **56by** other means, including maintaining physical security of our premises and physical and electronic security of our information technology systems. However, these security measures may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Adequate remedies may not exist in the event of unauthorized use or disclosure of our proprietary information. The disclosure of our trade secrets would impair our competitive position and may materially harm our business, financial condition and results of operations. Costly and time- consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and failure to maintain trade secret protection could adversely affect our competitive business position. In addition, others may independently discover or develop our trade secrets and proprietary information, and the existence of our own trade secrets affords no protection against such independent discovery. For example, a public presentation in the scientific or popular press on the properties of our product candidates could motivate a third party, despite any perceived difficulty, to assemble a team of scientists having backgrounds similar to those of our employees to attempt to independently reverse engineer or otherwise duplicate our antibody technologies to replicate our success. ~~60We~~ **We** may be subject to claims asserting that our employees, consultants or advisors have wrongfully used or disclosed alleged trade secrets of their current or former employers. Many of our employees, consultants or advisors are currently, or were previously, employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and advisors do not use the proprietary information or know- how of others in their work for us, we may be subject to claims that these individuals, or we, have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual' s current or former employer, or that patents and applications we have filed to protect inventions of these employees, even those related to one or more of our product candidates, are rightfully owned by their former or current employer. Litigation may be necessary to defend against these claims. For example, in 2021, a third party filed a

lawsuit in Federal court against the Company, and in 2022 claims were added to that lawsuit to add our Chief Executive Officer as a co- defendant with Company. This lawsuit alleges that our Chief Executive Officer breached contractual and fiduciary duties he owed to the plaintiff by, among other things, improperly utilizing plaintiff' s purported confidential information to benefit the Company' s business, including with respect to our discovery efforts. For more information regarding these proceedings, please refer to Note 8 to the Company' s Financial Statements. If we fail in defending claims of misappropriation and similar claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management. If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected. Any registered trademarks or trade names may be challenged, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively, and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely impact our financial condition or results of operations. Intellectual property rights do not necessarily address all potential threats. The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example: ● others may be able to make products that are similar to our product candidates but that are not covered by the claims of the patents that we own or license or may own in the future; **57** ● we, or any partners or collaborators, might not have been the first to make the inventions covered by the issued patent or pending patent application that we license or may own in the future; ● we, or any partners or collaborators, might not have been the first to file patent applications covering certain of our or their inventions; ● others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our owned or licensed intellectual property rights; ● it is possible that our pending licensed patent applications or those that we may own in the future will not lead to issued patents; ● issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors; ~~61~~ ● our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets; ● we may not develop additional proprietary technologies that are patentable; ● the patents of others may have an adverse effect on our business; and ● we may choose not to file a patent for certain trade secrets or know- how, and a third party may subsequently file a patent covering such intellectual property. Should any of these events occur, they could significantly harm our business, financial condition, results of operations and prospects. Risks Related to Reliance on Third PartiesWe rely or will rely on third parties to help conduct our ongoing and planned preclinical studies and clinical trials for ~~NC410, NC525,~~ LNCB74 and any future product candidates we develop. If these third parties do not successfully carry out their contractual duties, comply with regulatory requirements or meet expected deadlines, we may not be able to obtain marketing approval for or commercialize ~~NC410, NC525,~~ LNCB74 and any future product candidates we develop, and our business could be materially harmed. We currently do not have the ability to independently conduct preclinical studies that comply with GLP requirements. We also do not currently have the ability to independently conduct any clinical trials. The FDA and regulatory authorities in other jurisdictions require us to comply with regulations and standards, including cGCP, or requirements for conducting, monitoring, recording and reporting the results of clinical trials, in order to ensure that the data and results are scientifically credible and accurate and that the trial subjects are adequately informed of the potential risks of participating in clinical trials. We rely on medical institutions, clinical investigators, contract laboratories and other third parties, such as CROs, to conduct GLP- compliant preclinical studies and cGCP- compliant clinical trials on our product candidates properly and on time. While we have agreements governing their activities, we control only certain aspects of their activities and have limited influence over their actual performance. The third parties with whom we contract for execution of our GLP- compliant preclinical studies and our cGCP- compliant clinical trials play a significant role in the conduct of these studies and trials and the subsequent collection and analysis of data. These third parties are not our employees and, except for restrictions imposed by our contracts with such third parties, we have limited ability to control the amount or timing of resources that they devote to our current or future product candidates. Although we rely on these third parties to conduct our GLP- compliant preclinical studies and cGCP- compliant clinical trials, we remain responsible for ensuring that each of our preclinical studies and clinical trials is conducted in accordance with its investigational plan and protocol and applicable laws and regulations, and our reliance on the CROs does not relieve us of our regulatory responsibilities. Many of the third parties with whom we contract may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other drug development activities that ~~could~~ **58could** harm our competitive position. Further, under certain circumstances, these third parties may terminate their agreements with us upon as little as 10 days' prior written notice. Some of these agreements may also be terminated by such third parties under certain other circumstances. If the third parties conducting our preclinical studies or our clinical trials do not adequately perform their contractual duties or obligations, experience significant business challenges, disruptions or failures, including as a result of natural disasters or public health emergencies such as the COVID- 19 pandemic, do not meet expected deadlines, terminate their agreements with us or need to be replaced, or if the quality or accuracy of the data they obtain is compromised due to their failure to adhere to our protocols or to GLP and cGCP, or for any other reason, we may need to enter into new

arrangements with alternative third parties. This could be difficult, costly or impossible, and our preclinical studies or clinical trials may need to be extended, delayed, terminated or repeated. As a result, we may not be able to obtain regulatory approval in a timely fashion, or at all, for the applicable product candidate, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed. ~~62We~~ **We** may depend on third- party collaborators for the discovery, development and commercialization of certain of our current and future product candidates. If our collaborations are not successful, we may not be able to capitalize on the market potential of these product candidates **. We are co- developing LNCB74 under a 50: 50 cost sharing arrangement with LigaChem under the LigaChem Agreement. The LigaChem Agreement provides for the ability of either party to opt to cease co- funding development of a co- development product in exchange for accepting a lower share of any potential downstream revenues resulting from commercialization or partnering of the product. If LigaChem were to cease co- developing LNCB74 or any other future co- development product under the LigaChem Agreement, Company would retain have the right to move forward with the development of LNC74 or any other such co- development products at its own discretion. However, in such cases the Company would incur 100 % of the costs which might require a reassessment of our capital resources** . In the future, we may form or seek other strategic alliances, joint ventures or collaborations, or enter into additional licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to product candidates we develop. Our collaborations pose, and potential future collaborations involving our product candidates may pose, the following risks to us: ● collaborators may have significant discretion in determining the efforts and resources that they will apply to these collaborations; ● collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates; ● collaborators may not properly enforce, maintain or defend our intellectual property rights or may use our proprietary information in a way that gives rise to actual or threatened litigation or that could jeopardize or invalidate our intellectual property or proprietary information, exposing us to potential litigation or other intellectual property proceedings; ● collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; ● disputes may arise between a collaborator and us that cause the delay or termination of the research, development or commercialization of the product candidate, or that result in costly litigation or arbitration that diverts management attention and resources; ● a collaborator with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such products; ● if a present or future collaborator were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program under such collaboration could be delayed, diminished or terminated; ~~and~~ **and59** ● collaboration agreements may restrict our right to independently pursue new product candidates. If we enter into additional collaboration agreements and strategic partnerships or license our intellectual property, products or businesses, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations, which could delay our timelines or otherwise adversely affect our business. We also cannot be certain that, following a strategic transaction or license, we will achieve the revenue or net income that justifies such transaction. Any of the factors set forth above and any delays in entering into new collaborations or strategic partnership agreements related to any product candidate we develop could delay the development and commercialization of our product candidates, which would harm our business prospects, financial condition and results of operations. In the event a present or future collaborator terminates their agreement with us, we would be prevented from receiving the benefits of any such agreement, which could have a materially adverse effect on our results of operations. We may seek to establish additional collaborations and, if we are not able to establish them on commercially reasonable terms, we may have to alter our development and commercialization plans. The advancement of our product candidates and development programs and the potential commercialization of our current and future product candidates will require substantial additional cash to fund expenses. For some of our current or future product candidates, we may decide to collaborate with additional pharmaceutical and biotechnology companies with respect to development and potential commercialization. Any of these relationships may require us to incur non- ~~63recurring~~ -- **recurring** and other charges, increase our near- and long- term expenditures, issue securities that dilute our existing stockholders, or disrupt our management and business. We face significant competition in seeking appropriate strategic partners and the negotiation process is time- consuming and complex. Whether we reach a definitive agreement for other collaborations 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 collaborator' s evaluation of a number of factors. Those factors may include the design or results of clinical trials, the progress of our clinical trials, the likelihood of approval by 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, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate. Further, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for future product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view them as having the requisite potential to demonstrate safety and efficacy. We may also be restricted under existing collaboration agreements from entering into future agreements on certain terms with potential collaborators. Such exclusivity could limit our ability to enter into strategic collaborations with future 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. We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of the product candidate for which we are seeking to

collaborate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any marketing or sales activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue. ~~Risks~~ **60Risks** Related to Our BusinessWe are highly dependent on our key personnel, and if we are not successful in attracting, motivating and retaining highly qualified personnel, we may not be able to successfully implement our business strategy. We are highly dependent on members of our executive team. The loss of the services of any of them may adversely impact the achievement of our objectives. Any of our executive officers could leave our employment at any time, as all of our employees are " at- will " employees, and we do not have " key person " insurance on them. The loss of the services of one or more of our executive officers or of certain members of our SAB could impede the achievement of our research, development and commercialization objectives. Recruiting and retaining qualified employees, consultants and advisors for our business, including scientific and technical personnel, is critical to our success. We have observed an increasingly competitive labor market. Increased employee turnover and changes in the availability of our workers could result in increased costs. We may not be able to attract and retain personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies and academic institutions for skilled individuals. In addition, failure to succeed in preclinical studies, clinical trials or applications for marketing approval may make it more challenging to recruit and retain qualified personnel. The inability to recruit, 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, financial condition, results of operations and growth prospects. ~~64We~~ **We** face significant competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively. The biotechnology industry is intensely competitive and subject to rapid and significant technological change. Our current or future product candidates may face competition from major pharmaceutical companies, specialty pharmaceutical companies, universities and other research institutions and from products and therapies that currently exist or are being developed, some of which products and therapies we may not currently know about. Many of our competitors have significantly greater financial, manufacturing, marketing, product development, technical and human resources than we do. Large pharmaceutical companies, in particular, have extensive experience in clinical testing, obtaining marketing approvals, recruiting patients and manufacturing pharmaceutical products, and they may also have products that have been approved or are in late stages of development, and collaborative arrangements in our target markets with leading companies and research institutions. Established pharmaceutical companies may also invest heavily to accelerate discovery and development of novel compounds or to in- license novel compounds that could make the product candidates that we develop obsolete. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. As a result of all of these factors, our competitors may succeed in obtaining patent protection and / or FDA or other regulatory approval or discovering, developing and commercializing products in our field before we do, which could result in our competitors establishing a strong market position before we are able to enter the market. Our competitors may obtain FDA or other regulatory approval of their product candidates more rapidly than we may or may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize our product candidates or platform technologies. Our competitors may also develop drugs or discovery platforms that are more effective, more convenient, more widely used or less costly than our product candidates or, in the case of drugs, have a better safety profile than our product candidates. These competitors may also be more successful than us in manufacturing and marketing their products and have significantly greater financial resources and expertise in research and development. There are a large number of companies developing or marketing treatments for cancer, including many major pharmaceutical and biotechnology companies. Currently marketed oncology drugs and therapeutics range from traditional cancer therapies, including chemotherapy, to antibody- drug conjugates, such as Genentech' s Kadcyla, to immune checkpoint inhibitors targeting CTLA- 4, such as BMS' Yervoy, and PD- 1 / PD- L1, such as BMS' Opdivo, Merck & Co.' s Keytruda and Genentech' s Tecentriq, to T- cell- engager immunotherapies, such as Amgen' s Blincyto. Companies are also developing treatments targeting the Siglec family of proteins, such as Celldex Therapeutics and Palleon Pharmaceuticals, both of which are currently engaged in preclinical studies. In addition, numerous compounds are in clinical development for cancer treatment. Many of these companies are well- capitalized and have significant clinical experience (see " Business — Competition "). ~~Smaller~~ **61Smaller** and other early- stage companies may also prove to be significant competitors. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our current and future product candidates. In addition, the biopharmaceutical industry is characterized by rapid technological change. If we fail to stay at the forefront of technological change, we may be unable to compete effectively. Technological advances or products developed by our competitors may render our product candidates obsolete, less competitive or not economical. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient, have a broader label, are marketed more effectively, are reimbursed or are less expensive than any products that we may develop. Our competitors may also obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize our product candidates or platform technologies. Even if our product candidates achieve marketing approval, they may be priced at a significant premium over competitive products if any have been approved by then, resulting in reduced competitiveness. If we do not compete successfully, we may not generate or derive sufficient revenue from any product candidate for which we obtain marketing approval and may not become or remain profitable. ~~65We~~ **We** may need to grow the size of our organization, and we may experience difficulties in managing future growth. As our development plans and strategies

develop, we may need additional managerial, operational, marketing, sales, financial and other personnel. Future growth would impose significant added responsibilities on members of management, including: ● identifying, recruiting, integrating, maintaining and motivating additional employees; ● managing our internal development efforts effectively, including the clinical and FDA review process for ~~NC410,~~ LNCB74 and any future product candidates we develop, while complying with our contractual obligations to contractors and other third parties; and ● improving our operational, financial and management controls, reporting systems and procedures. Our future financial performance and our ability to advance development of and, if approved, commercialize ~~NC410,~~ LNCB74 and any future product candidates we develop will depend, in part, on our ability to effectively manage any future growth, and our management may have to divert a disproportionate amount of its attention away from day- to- day activities in order to devote a substantial amount of time to managing these growth activities. We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors and consultants to provide certain services. We cannot assure you that the services of independent organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by consultants is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain marketing approval of any current or future product candidates or otherwise advance our business. We cannot assure you that we will be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, or at all. If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, we may not be able to successfully implement the tasks necessary to further develop and commercialize ~~NC410,~~ LNCB74 and any future product candidates we develop and, accordingly, may not achieve our research, development and commercialization goals. If we are unable to establish marketing, sales and distribution capabilities for ~~NC410,~~ LNCB74 or any other product candidate that may receive regulatory approval, we may not be successful in commercializing those product candidates if and when they are approved. We do not have sales or marketing infrastructure. To achieve commercial success for ~~NC410,~~ LNCB74 and any other product candidate for which we may obtain marketing approval, we will need to establish a sales and marketing organization. In the future, we expect to build a focused sales and marketing infrastructure to market some of our product ~~candidates~~ **62candidates** in the United States, if and when they are approved. There are risks involved with establishing our own marketing, sales and distribution capabilities. For example, recruiting and training a sales force is expensive and time consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel. Factors that may inhibit our efforts to market our products on our own include: ● our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel; ● the inability of sales personnel to obtain access to physicians in order to educate physicians about our product candidates, once approved; ● the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; ~~and66~~ -- **and** ● unforeseen costs and expenses associated with creating an independent sales and marketing organization. If we are unable to establish our own marketing, sales and distribution capabilities and are forced to enter into arrangements with, and rely on, third parties to perform these services, our revenue and our profitability, if any, are likely to be lower than if we had developed such capabilities ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell, market and distribute our product candidates or may be unable to do so on terms that are favorable to us. We likely will have ~~little~~ **limited** control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we do not establish marketing, sales and distribution capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates. Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of our product candidates. We face an inherent risk of product liability exposure related to the testing of our product candidates in human trials and may face greater risk if we commercialize any products that we develop. Product liability claims may be brought against us by subjects enrolled in our trials, patients, healthcare providers or others using, administering or selling our products. If we cannot successfully defend ourselves against such claims, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in: ● decreased demand for any product candidate we may develop; ● withdrawal of trial participants; ● termination of clinical trial sites or entire trial programs; ● injury to our reputation and significant negative media attention; ● initiation of investigations by regulators; ● significant time and costs to defend the related litigation; ● substantial monetary awards to trial subjects or patients; ● diversion of management and scientific resources from our business operations; and ● the inability to commercialize any product candidates that we may develop. ~~While~~ **63While** we currently hold trial liability insurance coverage consistent with industry standards, the amount of coverage may not adequately cover all liabilities that we may incur. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. We intend to expand our insurance coverage for products to include the sale of commercial products if we obtain marketing approval for our product candidates, but we may be unable to obtain commercially reasonable product liability insurance. A successful product liability claim or series of claims brought against us, particularly if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business and financial condition. Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud. We are subject to the periodic reporting requirements of the Exchange Act. We designed our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well- conceived and operated,

can provide only reasonable, not absolute, assurance that the objectives of the control system are met. ~~67These --~~ **These** inherent limitations include the realities that judgments in decision- making can be faulty, and that breakdowns can occur because of simple errors or mistakes. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected. Our ability to use our net operating loss carryforwards to offset future taxable income may be subject to certain limitations. We have incurred substantial losses during our history and do not expect to become profitable in the near future, and we may never achieve profitability. To the extent that we continue to generate taxable losses, unused losses will carry forward to offset future taxable income, if any, until such unused losses expire. As of December 31, ~~2023~~ **2024**, we had federal and state net operating loss carryforwards of $ ~~203~~ **230**. ~~9~~ **1** million and $ ~~208~~ **234**. ~~5~~ **8** million, respectively. Certain federal and state net operating loss carryforwards will begin to expire, if not utilized, by ~~2036~~ **2037**. Limitations imposed by the applicable jurisdictions on our ability to utilize net operating loss carryforwards could cause income taxes to be paid earlier than would be paid if such limitations were not in effect and could cause such net operating loss carryforwards to expire unused, in each case reducing or eliminating the benefit of such net operating loss carryforwards. Furthermore, we may not be able to generate sufficient taxable income to utilize our net operating loss carryforwards before they expire. If any of these events occur, we may not derive some or all of the expected benefits from our net operating loss carryforwards. In addition, we may experience ownership changes in the future as a result of subsequent shifts in our stock ownership, some of which may be outside of our control. As a result, even if we earn net taxable income, our ability to use our net operating loss and tax credit carryforwards may be materially limited, which could harm our future operating results by effectively increasing our future tax obligations. Natural disasters or other unexpected events may disrupt our operations, adversely affect our results of operations and financial condition, and may not be covered by insurance. The occurrence of one or more unexpected events, including fires, tornadoes, tsunamis, hurricanes, earthquakes, floods, and other forms of severe hazards in the United States or in other countries in which we or our suppliers or manufacturers operate or are located could adversely affect our operations and financial performance. These types of unexpected events could result in physical damage to and complete or partial closure of one or more of the manufacturing facilities operated by our contract manufacturers, or the temporary or long- term disruption in the supply of products, and / or disruption of our ability to deliver products to customers. Further, the long- term effects of climate change on general economic conditions and the pharmaceutical manufacturing and distribution industry in particular are unclear, and changes in the supply, demand or available sources of energy and the regulatory and other costs associated with energy production and delivery may affect the availability or cost of goods and services, including natural resources, necessary to run our businesses. Existing insurance arrangements may not provide protection for the costs that may arise from such events, particularly if such events are catastrophic in nature or occur in combination. Any long- term disruption in our ability to service our customers from one or more distribution centers or outsourcing facilities could have a material adverse effect on our operations, our business, results of operations and stock price. ~~Failure to meet investor and stakeholder expectations regarding environmental, social and corporate governance, or " ESG " matters may damage our reputation. There is an increasing focus from certain investors, customers, consumers, employees and other stakeholders concerning ESG matters. Additionally, public interest and legislative pressure related to public companies' ESG practices continue to grow. If our ESG practices fail to meet investor, customer, consumer, employee or other stakeholders' evolving expectations and standards for responsible corporate citizenship in areas including environmental stewardship, Board of Directors and employee diversity, human capital management, corporate governance and transparency, our reputation, brand, appeal to investors and employee retention may be negatively impacted, which could have a material adverse effect on our business or financial condition.~~ 68Risks **64Risks** Related to Our Common StockThe price of our common stock has been and may continue to be volatile and fluctuate substantially. Our stock price has been and is likely to remain volatile. The stock market in general, and the market for biopharmaceutical companies in particular, have experienced extreme volatility that has often been unrelated to the operating performance or prospects of particular companies. As a result of this volatility, you may not be able to sell your common stock at or above a recently reported price, or at all. The market price for our common stock may be influenced by many factors, including: ● the commencement, enrollment or results of our ongoing or future clinical trials, or changes in the development status of our product candidates; ● any delay in our regulatory filings for our product candidates and any adverse development or perceived adverse development with respect to the applicable regulatory authority' s review of such filings, including without limitation the FDA' s issuance of a " refusal to file " letter or a request for additional information; ● adverse results or delays in clinical trials; ● our decision to initiate a clinical trial, not to initiate a clinical trial or to terminate an existing clinical trial; ● adverse regulatory decisions, including failure to receive regulatory approval of our product candidates; ● our failure to commercialize our product candidates; ● unanticipated serious safety concerns related to the use of our product candidates; ● the size and growth of our target markets; ● the success of competitive products or technologies; ● regulatory actions with respect to our product candidates or our competitors' products or product candidates; ● announcements by us or our competitors of significant acquisitions, strategic collaborations, joint ventures, collaborations or capital commitments; ● regulatory or legal developments in the United States and other countries applicable to our product candidates, including but not limited to clinical trial requirements for approvals; ● our inability to obtain adequate product supply for any approved product or inability to do so at acceptable prices; ● developments or disputes concerning patent applications, issued patents or other proprietary rights; ● the recruitment or departure of key personnel; ● the level of expenses related to our product candidates or clinical development programs; ● the results of our efforts to discover, develop, acquire or in- license product candidates; ● actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts or publications of research reports about us or our industry; ● variations in our annual or quarterly financial results or those of companies that are perceived by investors to be similar to us; ~~69~~ **65** ● our cash position; ● fluctuations in the valuation of companies perceived by investors to be comparable to us; ● share price and volume fluctuations

attributable to inconsistent trading volume levels of our shares; ● announcement or expectation of additional financing efforts; ● sales of our common stock by us, our directors, officers or their affiliated funds or our other stockholders; ● changes in the structure of healthcare payment systems; ● significant lawsuits, including intellectual property or stockholder litigation; ● market conditions in the pharmaceutical and biotechnology sectors; ● general economic, industry and market conditions; and ● other events or factors, many of which are beyond our control, or unrelated to our operating performance or prospects. In addition, the stock market in general, and Nasdaq and biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. The realization of any of the above risks or any of a broad range of other risks, including those described in this " Risk Factors " section, could have a dramatic and material adverse impact on the market **price of our common stock. We are currently not in compliance with the continued listing standards of the Nasdaq Global Select Market, and if we are unable to regain compliance, our common stock will be delisted from the exchange. On January 31, 2025, the Company received written notice (the " Notice ") from the Listing Qualifications Department of The Nasdaq Stock Market, LLC (" Nasdaq ") notifying us that the closing price of our common stock over the prior 30 consecutive business days had fallen below $ 1. 00 per share, which is the minimum average closing price required to maintain listing on the Nasdaq Global Select Market under Nasdaq Listing Rule 5450 (a) (1) (the " Minimum Bid Requirement "). Beginning on December 17, 2024, the Company' s closing bid price of its Common Stock has been below $ 1. 00 per share. The deficiency letter does not result in the immediate delisting of our common stock from the Nasdaq Global Select Market. In accordance with Nasdaq Listing Rule 5810 (c) (3) (A), we have been provided an initial period of 180 calendar days, or until July 30, 2025 (the " Compliance Date "), to regain compliance with the Bid Price Rule. If, at any time before the Compliance Date, the bid price for our common stock closes at $ 1. 00 per share or more for a minimum of 10 consecutive business days, as required by the Compliance Period Rule, the Staff will provide written notification to us that we comply with the Bid Price Rule, unless the Staff exercises its discretion to extend this 10- day period pursuant to Nasdaq Listing Rule 5810 (c) (3) (H). If we do not regain compliance with the Bid Price Rule by the Compliance Date, we may be eligible for an additional 180 calendar day compliance period. To qualify, we would be required to transfer the listing of our common stock to the Nasdaq Capital Market, provided that we meet the continued listing requirements for the market value of publicly held shares and all other initial listing standards of the Nasdaq Capital Market, with the exception of its bid requirement. To effect such a transfer, among other things, we would also need to pay an application fee to Nasdaq and provide written notice to the Staff of our intention to cure the deficiency during the additional compliance period by effecting a reverse stock split, if necessary. If we do not regain compliance with the Bid Price Rule by the Compliance Date and it appears to the Staff that we will not be able to regain compliance with the Bid Price Rule during the additional compliance period, or for other reasons, we are otherwise not eligible for an additional compliance period at that time, the Staff will provide written notification to us that our common stock will be subject to delisting. At that time, we may appeal the Staff' s delisting 66determination to a Nasdaq Listing Qualifications Panel (the " Panel "). We expect that our common stock would remain listed pending the Panel' s decision. However, there can be no assurance that, if we do appeal the delisting determination by the Staff to the Panel, that such appeal would be successful. We intend to monitor the closing bid price of our common stock and may, if appropriate, consider available options to regain compliance with the Bid Price Rule, which could include seeking to affect a reverse stock split. However, there can be no assurances that we will be able to regain compliance with the Bid Price Rule. There are many factors that may adversely affect our minimum bid price, including those described throughout this " Risk Factors " section. Many of these factors are outside of our control. As a result, we may not be able to sustain compliance with the Bid Price Rule in the long term. Any potential delisting of our common stock from the Nasdaq Global Select Market would likely result in decreased liquidity and increased volatility for our common stock and would adversely affect our ability to raise additional capital or to enter into strategic transactions. Any potential delisting of our common stock from the Nasdaq Global Select Market would make it more difficult for our stockholders to sell our common stock in the public market. Further, if the Company seeks to implement a reverse stock split in order to remain listed on the Nasdaq Global Select Market, the announcement or implementation of such a reverse stock split could negatively affect the** price of our common stock. If securities analysts do not publish research or reports about our business or if they publish inaccurate or unfavorable research about our business, the price of our stock could decline. The trading market for our common stock relies, in part, on the research and reports that industry or financial analysts publish about us or our business. We currently receive only limited coverage by equity research analysts. If additional analysts do not commence coverage of us, the trading price of our stock could decrease. In addition, if one or more of the analysts covering our business issue adverse reports about us or downgrade their evaluations of our stock, the price of our stock could decline. If one or more of these analysts cease to cover our stock or fail to publish reports on us regularly, we could lose visibility in the market for our stock, which, in turn, could cause our stock price to decline. Sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall, even if our business is doing well. If our existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market, the market price of our common stock could decline significantly. We have filed registration statements on Form S- 8 shares of common stock that are either subject to options or other equity awards issued or reserved for future issuance under our equity incentive plans. The number of shares available for issuance under the 2019 Omnibus Plan is subject to an automatic annual increase on January 1st of each year, continuing until the expiration of the 2019 Omnibus Plan, in an amount equal to four percent (4 %) of the total number of shares of Common Stock outstanding on December 31st of the preceding calendar year. The number of shares available for issuance under the 2019 Employee Stock Purchase Plan, or " ESPP ", is subject to an automatic annual increase on January 1st of each year, continuing

until the expiration of the ESPP, in an amount equal to the least of (i) one percent (1 %) of the total number of shares of Common Stock outstanding on December 31st of the preceding calendar year, (ii) 480, 000 shares of Common Stock (subject to the capitalization adjustment provisions included in the ESPP) and (iii) a number of shares of Common Stock determined by the administrator of the ESPP. Shares registered under our registration statements on Form S- 8 will be available for sale in the public market subject to vesting arrangements and exercise of options and the restrictions of Rule 144 in the case of our affiliates. ~~70Our~~ -- **Our** executive officers, directors and current beneficial owners of 5 % or more of our common stock and their respective affiliates exercise significant influence over our company, which limits your ability to influence corporate matters and could delay or prevent a change in corporate control. Our executive officers, directors and current beneficial owners of 5 % or more of our common stock and their respective affiliates beneficially own, in the aggregate, approximately ~~18~~ **25** % of our outstanding common stock. As a result, these stockholders, if they act together, will be able to influence our management and affairs and the outcome of matters submitted to our stockholders for approval, including the election of directors and any sale, merger, consolidation or sale ~~of~~ **67of** all or substantially all of our assets. This concentration of ownership might adversely affect the market price of our common stock by: ● delaying, deferring or preventing a change of control of us; ● impeding a merger, consolidation, takeover or other business combination involving us; or ● discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of us. We had and may in the future be subject to securities litigation, which can be expensive and could divert management' s attention. Litigation is often expensive and can divert management' s attention and resources from other business concerns, which could adversely affect our business. If we are ultimately required to pay significant defense costs, damages or settlement amounts, such payments could adversely affect our operations. We have been and may be the target of securities litigation in the future. The market price of our common stock has experienced and may continue to experience volatility, and in the past, companies that have experienced volatility in the market price of their stock have been subject to securities litigation. Any future litigation could result in substantial costs and divert our management' s attention from other business concerns, which could seriously harm our business. If we are ultimately required to pay significant defense costs, damages or settlement amounts, such payments could adversely affect our operations. While we maintain liability insurance, costs or expenses associated with litigation may exceed our insurance coverage, and we may be forced to bear some or all costs and expenses directly, which could be substantial. Anti- takeover provisions in our charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management. Provisions in our amended and restated certificate of incorporation and amended and restated bylaws may delay or prevent an acquisition of us or a change in our management. For example, our board of directors has the authority to issue up to 10, 000, 000 shares of preferred stock. The board of directors can fix the price, rights, preferences, privileges and restrictions of the preferred stock without any further vote or action by our stockholders. The issuance of shares of preferred stock may delay or prevent a change of control transaction. As a result, the market price of our common stock and the voting and other rights of our stockholders may be adversely affected. An issuance of shares of preferred stock may result in the loss of voting control to other stockholders. These provisions also include a classified board of directors, a prohibition on actions by written consent of our stockholders and the ability of our board of directors to issue preferred stock without stockholder approval. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which limits the ability of stockholders owning in excess of 15 % of our outstanding voting stock to merge or combine with us. Although we believe these provisions collectively provide for an opportunity to obtain greater value for stockholders by requiring potential acquirers to negotiate with our board of directors, they would apply even if an offer rejected by our board were considered beneficial by some stockholders. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management. ~~71If~~ **If** we fail to maintain proper and effective internal control over financial reporting, our ability to produce accurate and timely financial statements could be impaired, investors may lose confidence in our financial reporting and the trading price of our common stock may decline. ~~When~~ **Effective December 31, 2024,** we ~~lose our status~~ **no longer qualify** as an " emerging growth company, " ~~our independent registered~~ **meaning we can no longer rely on certain exemptions from various** public **company** ~~accounting firm will be required to attest to the effectiveness of our internal control over financial~~ reporting **requirements, including having** ~~pursuant to Section 404 of the Sarbanes Oxley Act. The rules governing the standards that must be met for management to assess our internal control over financial reporting are complex and~~ - **an extended transition period to** ~~require significant documentation, testing and possible remediation. To~~ comply with ~~the requirements of being~~ **new or revised accounting standards applicable to public companies. We maintained our status as** a **smaller** reporting company **; thus** ~~under the Exchange Act~~ , ~~we will need to implement additional financial and management controls, reporting systems and procedures and hire additional accounting and finance staff. We cannot assure you that there will not be material weaknesses or~~ **our** ~~significant deficiencies in our internal control over financial reporting in the future. Our~~ independent registered public accounting firm will not be required to provide an attestation report on the effectiveness of our internal control over financial reporting **. This** ~~so long as we qualify as an " emerging growth company, " which~~ may increase the risk that material weaknesses or significant deficiencies in our internal control over financial reporting go undetected. Any failure ~~to~~ **68to** maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations or cash flows. If we are unable to conclude that our internal control over financial reporting is effective, ~~or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal control over financial reporting,~~ investors may lose confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could

also restrict our future access to the capital markets. We do not intend to pay dividends on our common stock, so any returns will be limited to the value of our stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to stockholders will therefore be limited to the appreciation of their stock. We have incurred and will continue to incur significantly increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives. As a public company we have incurred, and we expect ~~, particularly after we are no longer an emerging growth company,~~ to continue to incur significant legal, accounting, investor relations and other expenses that we did not incur as a private company. The Sarbanes- Oxley Act, the Dodd- Frank Wall Street Reform and Consumer Protection Act, the listing requirements of Nasdaq and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel devote a substantial amount of time to these compliance initiatives. We expect these rules and regulations to substantially increase our legal and financial compliance costs and to make some activities more time consuming and costly. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain sufficient coverage. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers. These rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. ~~72~~ **Our amended and restated bylaws designate the Court of Chancery of the State of Delaware or the United States District Court for the District of Delaware as the exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees. Our Second Aamended and Restated Bylaws (Bylaws) provide that, unless we consent in writing to an alternative forum, the Court of Chancery of the State of Delaware or, if subject matter jurisdiction over the matter that is the subject of such action is vested exclusively in the federal courts, the United States District Court for the District of Delaware will, to the fullest extent permitted by law, be the sole and exclusive forum for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of a fiduciary duty owed by any of our current or former directors, officers and employees, (iii) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law, our certificate of incorporation or our bylaws, (iv) any action or proceeding to interpret, apply, enforce or determine the validity of our certificate of incorporation or the bylaws or (v) any action asserting a claim that is governed by the internal affairs doctrine, in each case subject to the Court of Chancery or the United States District Court for the District of Delaware, as applicable, having personal jurisdiction over the indispensable parties named as defendants therein. In addition, any person holding, owning or otherwise acquiring any interest in any of our securities shall be deemed to have notice of and to have consented to this provision of our bylaws. The choice of forum provision does not apply to any actions arising under the Securities Act or the Exchange Act. The choice of forum provision may limit a stockholder' s ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or employees, which may discourage such lawsuits against us and our directors, officers and employees even though an action, if successful, might benefit our stockholders. Stockholders who do bring a claim in the Court of Chancery or the United States District Court for the District of Delaware could face additional litigation costs in pursuing any such claim, particularly if they do not reside in or near the jurisdiction. The Court of Chancery or the United States District Court for the District of Delaware may also reach different judgments or results than would other courts, including courts where a** 69