Risk Factors Comparison 2025-03-06 to 2024-03-25 Form: 10-K

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The following is a summary of the key risks relating to the Company. A more detailed description of each of the risks can be found below under Item 1A. Risk Factors. Risks Related to Our Financial Position and Capital Requirements ● Our consolidated financial statements as of December 31, ~~2023~~ **2024** have been prepared ~~under the assumption~~ --- **assuming** that we will continue as a going concern for the next twelve months. ● We will need to raise additional capital to operate our business. ● We expect to continue to incur significant operating and capital expenditures and we will need additional funds ~~to support our operations~~. ● The actual amount of funds we will need to operate is subject to many risk factors, some of which are beyond our control. ● We currently have a limited operating history as an oncology company, no products approved for commercial sale, have no significant source of revenue and may never generate significant revenue. ● ~~We~~ **In the past we** have identified material weaknesses in our internal controls ~~, and we cannot provide assurances that these weaknesses will be effectively remediated or that additional material weaknesses will not occur in the future~~. ● We expect to seek to raise additional capital in the future, which may be dilutive to stockholders ~~or impose operational restrictions~~. ● Our operating results may fluctuate significantly, which makes our future operating results difficult to predict. ● If our acquired intangible assets become impaired, we may be required to record a significant charge to earnings. Risks Related to Our Business ● Prior to 2022 we did not conduct any ~~cancer~~ research and development activities **directed to cancer diagnosis, treatment or prevention** and there can be no assurance that we will successfully be able to do so. ● The development and commercialization of oncolytic viruses have experienced certain challenges. ● Our research and development efforts may not succeed in developing successful products and technologies. ● We may not realize the benefits from any strategic alliances we form or licensing arrangements we enter into. ● We may not be able to retain rights licensed to us by others to commercialize key products and may not be able to establish or maintain the relationships we need to develop, manufacture, and market our products. ● We may incur additional expenses in connection with our licenses and collaboration arrangements and our development of our product candidates. ● Developments by competitors may render our products or technologies obsolete or non- competitive. ● We may seek to selectively establish collaborations, and, if we are unable to establish them on commercially reasonable terms, we may have to alter our development and commercialization plans. ● If the parties we depend on for product manufacturing are unsuccessful in providing adequate drug supply, or if existing drug supply becomes unusable, it may delay or impair our ability to develop, manufacture and market our product candidates. ● Any problems obtaining the standard of care drugs that we administer with VCN- 01, could result in a **trial** delay or interruption ~~in our clinical trials~~. ● We may fail to retain or recruit necessary personnel, and we may be unable to secure the services of consultants. ● Global health crises **or other disruptions to global trade and supply lines** may adversely affect our planned operations. ● Business disruptions could seriously harm our future revenue and financial condition and increase costs and expenses. ● Unfavorable economic conditions could adversely affect our business, financial condition or results of operations. ● We rely extensively on our information technology systems which are vulnerable to risks, including cybersecurity and data leakage risks. ● Our business and operations would suffer in the event of computer system failures. ● Any failure to maintain the security of information relating to our patients, customers, employees and suppliers, whether as a result of cybersecurity attacks or otherwise, could expose us to litigation, government enforcement actions and costly response measures, and could disrupt our operations and harm our reputation. ● We may face particular data protection, data security and privacy risks in connection with the European Union' s Global Data Protection Regulation and other privacy regulations. Regulatory Risks ● If we do not obtain the necessary regulatory approvals we may not be able to develop or sell our product candidates. ● Clinical trials are very expensive, time consuming, and difficult to design and implement. ● The results of our clinical trials may not support our proposed product candidate claims and the results of preclinical studies and completed clinical trials are not necessarily predictive of future results. ● Difficulties in enrolling, retaining, or completing patients in our clinical trials or delays in enrollment are expected to result in our clinical development activities being delayed or otherwise adversely affected. ● Patients who are administered our product candidates may experience unexpected side effects or other safety risks that could cause a halt in clinical development, preclude approval or limit the commercial potential of the product candidate. ● It is possible that we may not be able to obtain or maintain orphan drug designation or exclusivity for our drug candidates ~~,~~. **● Fast Track designation by the FDA does not assure FDA approval. ● We may not be eligible to receive a priority review voucher despite rare pediatric disease designation for VCN- 01** ● Our product candidates, if approved for sale, may not gain acceptance among physicians, patients and the medical community. ● We depend on third parties, including researchers and sublicensees, who are not under our control. ● We currently have no marketing, sales or distribution organization and have no experience in marketing products as a company. ● Reimbursement may not be available for our product candidates, which would impede sales. ● Healthcare reform measures could hinder or prevent our product candidates' commercial success. ● If we fail to comply with state and federal healthcare regulatory laws, we could face substantial penalties, damages, fines, disgorgement, exclusion from participation in governmental healthcare programs, and the curtailment of operations, any of which could harm our business. ● If we obtain approval to commercialize our clinical product candidates outside of the United States, a variety of risks associated with international operations could harm our business ● If product liability lawsuits are successfully brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates. Intellectual Property Risks ● We rely on patent applications and various regulatory exclusivities to protect some of our product candidates and our ability to compete may be limited or eliminated if we are not able to protect our products. **4** ● We may incur substantial costs as a result of litigation or other proceedings relating to

protecting our intellectual property rights, as well as costs associated with lawsuits. ● If we infringe the rights of others, we could be prevented from selling products or forced to pay damages. ~~4~~ ● We enjoy restricted geographical protection with respect to certain patents. ● We may become subject to claims challenging inventorship ~~or ,~~ ownership **or validity** of our patents and other intellectual property ~~.~~ ● Risks Related to Our Securities ● We cannot assure you that our common stock will be liquid or that it will remain listed on the NYSE American exchange. ● We expect to seek to raise additional capital in the future, which may be dilutive to stockholders or impose operational restrictions. ● The market price of our common stock has been and may continue to be volatile and adversely affected by various factors. ● Our Articles of Incorporation and bylaws and Nevada law have anti- takeover effects that could discourage, delay or prevent a change in control, which may cause our stock price to decline. ● We do not intend to pay dividends in the foreseeable future on our common stock. ● Resales of our common stock in the public market by our stockholders may cause the market price of our common stock to fall. ● The shares of common stock offered under our current Amended and Restated At The Market Issuance Sales Agreement may be sold in " at the market " offerings, and investors who buy shares at different times will likely pay different prices. ~~Item~~ **5Item** 1. Business. OverviewWe are a diversified clinical- stage company developing therapeutics designed ~~ot~~ **to** treat cancer and related diseases in areas of high unmet need. As a result of the acquisition in March 2022 of Theriva Biologics, S. L. (" VCN ", formerly named VCN Biosciences, S. L.), described in more detail below (the " Acquisition "), we ~~began transitioning~~ **transitioned** our strategic focus to oncology ~~, which is now our primary focus,~~ through the development of VCN' s new oncolytic adenovirus platform designed for intravenous and intravitreal delivery to trigger tumor cell death, to improve access of co- administered cancer therapies to the tumor, and to promote a robust and sustained anti- tumor response by the patient' s immune system. ~~Our lead product candidate, VCN- 01, a clinical stage oncolytic human adenovirus that is modified to express an enzyme, PH20 hyaluronidase, is currently being administered in a Phase 2 clinical study for the treatment of pancreatic cancer, a Phase 1 clinical study for the treatment of retinalblastoma, a Phase 1 clinical study for the treatment of head and neck squamous cell carcinoma and a Phase 1 clinical study for the treatment of solid tumors.~~ Prior to the Acquisition, our focus was on developing therapeutics designed to treat gastrointestinal (GI) diseases which included our clinical development candidates: (1) SYN- 004 (ribaxamase) which is designed to degrade certain commonly used intravenous (IV) beta- lactam antibiotics within the GI tract to prevent microbiome damage ~~,~~ thereby preventing overgrowth and infection by pathogenic organisms such **as** Clostridioides difficile infection (CDI) **,** and vancomycin resistant Enterococci (VRE), and reducing the incidence and severity of acute graft- versus- host- disease (aGVHD) in allogeneic hematopoietic cell transplant (HCT) recipients, and (2) SYN- 020, a recombinant oral formulation of the enzyme intestinal alkaline phosphatase (IAP) produced under cGMP conditions and intended to treat both local GI and systemic diseases. As part of our strategic transformation into an oncology focused company, we are exploring value creation options for our SYN- 004 and SYN- 020 assets, including out- licensing or partnering. ~~5Our~~ - **Our** Current Product Pipeline * Based on management' s current beliefs and expectationsallo- HCT allogeneic hematopoietic cell transplant. ~~CPI immune checkpoint inhibitor~~ **CSR clinical study report** . HNSCC head and neck squamous cell carcinoma. IV intravenous. IVit intravitreal ~~. ODD Orphan Drug Designation~~ . For other abbreviations see the text. [1]Additional products with preclinical proof- of- concept include SYN- 006 (carbapenemase) to prevent aGVHD **, CDI,** and ~~infection by~~ **microbiome damage in patients treated with** carbapenem **antibiotics** ~~resistant enterobacteriaceae~~ and SYN- 007 (ribaxamase) DR to prevent antibiotic associated diarrhea with oral β- lactam antibiotics. [2]Depending on funding / partnership. SYN- 004 may enter **a U. S. Food** ~~an~~ **and Drug Administration (" FDA ")** - agreed Phase 3 clinical trial for the treatment of CDI. ~~[3]We have an option- license agreement with Massachusetts General Hospital to develop SYN- 020 in several potential indications related to inflammation and gut barrier dysfunction. 4We have an option agreement with Sant Joan de Déu- Barcelona Children' s Hospital to license their intellectual property rights related to the use of VCN- 01 in combination with topoisomerase I inhibitor chemotherapies for the treatment of cancer. Our~~ **6Our** Current Oncology- Focused PipelineOncolytic VirusesOur oncology platform is based on oncolytic virotherapy (" OV therapy "), which exploits the ability of certain viruses to kill tumor cells and trigger an anti- tumor immune response. This novel class of anticancer agents has unique mechanisms of action compared to other cancer drugs. Oncolytic viruses **(" OV ")** exploit the fact that cancer cells contain mutations that cause them to lose growth control and form tumors. Once inside a tumor cell, oncolytic viruses exploit the tumor cell machinery to generate thousands of additional copies of the virus, which then kill the tumor cell and spread to neighboring cells, causing a chain reaction of cell killing. This infection and tumor cell killing by OVs also alerts the immune system, which can then attack the virus infected tumor cells to help destroy the tumor in some instances. Our OV product candidates are engineered to efficiently infect and selectively replicate to a high extent in tumor cells versus normal host cells, which enables intravenous delivery. By contrast, many other oncolytic viruses in clinical development today are administered by direct injection into the tumor. Intravenous delivery has the potential to expand the therapeutic effect of OVs because the virus can infect both the primary tumor and tumor metastases throughout the body. ~~6Our~~ - **Our** first product candidate ~~,~~ VCN- 01, is a clinical stage oncolytic human adenovirus that is modified to express an enzyme, PH20 hyaluronidase, that **is designed to** ~~degrades~~ - **degrade** hyaluronan in the tumor stroma, which helps the virus and other molecules to penetrate and spread throughout the tumor. VCN- 01 can be used alone or in combination with other cancer therapies, such as chemotherapy and immunotherapy, for difficult to treat cancers. An expanding intellectual property portfolio supports our oncology programs, and because our products are characterized as biologics with Orphan Drug designation in our target indications, **if approved by the FDA** they will be further protected by data and / or market exclusivity ~~in major markets~~ . VCN- 01 — An oncolytic human type- 5 adenovirus engineered for intravenous administration and to express a tumor matrix degrading enzyme (PH20 hyaluronidase) that facilitates the entry of therapeutics and immune cells into tumorsVCN- 01 is a genetically modified oncolytic adenovirus that has been engineered to contain four independent genetic modifications on the backbone of the wild- type human adenovirus serotype 5 (HAd5) genome. These modifications have been shown in preclinical and clinical studies to confer tumor selective replication and antitumor activity. VCN- 01 was engineered to replicate in and kill virtually all types of solid tumor cells, to expose tumor neoantigens of lysed tumors, to reduce liver tropism, and to express PH20

hyaluronidase to enhance the penetration of virus, chemotherapy, immuno- oncology therapy, and immune cells into the tumor. Malignant tumors are made up of tumor cells as well as significant supporting tissue known as tumor stroma. The tumor stroma supports the formation and growth of tumors and contains cells and other components that are required for robust tumor growth and metastasis. The stroma also forms an effective barrier to the entry of therapeutic agents such as chemotherapy and immuno- oncology products. A key structural component of the tumor stroma is hyaluronic acid, and tumor levels of hyaluronic acid have been clinically associated with reduced survival in metastatic pancreatic cancer patients. VCN- 01 is designed to overcome the stroma barrier problem by expressing the hyaluronan degrading enzyme PH20 hyaluronidase after it infects tumor cells. Expression of PH20 by VCN- 01 is designed to degrade the hyaluronic acid within the tumor stroma and **to** ~~improves~~ **improve** virus spread throughout the tumor. Based upon the foregoing, we believe our oncolytic virus platform, exemplified by VCN- 01, represents a new and potentially powerful form of therapy ~~that~~ **to be** ~~combines~~ **combined with** tumor cell killing, anti- tumor immunity and stroma destruction after intravenous delivery. The VCN- 01 product candidate is provided as a sterile liquid concentrate that is diluted for infusion or injection. The proposed therapeutic indication for VCN- 01 is the treatment of solid tumors, as its selectivity mechanism relies on cellular properties shared by virtually all human tumor cells. Our initial indication for clinical development is unresectable metastatic pancreatic cancer, a disease for which there is currently no cure and only limited therapeutic options. VCN- 01 has been administered to ~~116~~ **142** patients across multiple Phase 1 clinical trials and **the** Phase 2 VIRAGE trial, including patients with pancreatic cancer, head and neck squamous cell carcinoma, ovarian ~~carcinoma~~ **cancer** , colorectal cancer, and retinoblastoma. ~~Pancreatic~~ **7Pancreatic** Ductal Adenocarcinoma Cancer of the pancreas consists of two main histological types: cancer that arises from the ductal (exocrine) cells of the pancreas or, much less often, cancers may arise from the endocrine compartment of the pancreas. Pancreatic ductal adenocarcinoma (“ PDAC ”) accounts for more than 90 % of all pancreatic tumors. It can be located either in the head of the pancreas or in the body- tail. Pancreatic cancer usually ~~metastasizess~~ **metastasizes** to the liver and peritoneum. Other less common metastatic sites are the lungs, brain, kidney and bone. In its early stages, pancreatic cancer does not typically result in any characteristic symptoms. In many instances, progressive abdominal pain is the first symptom. Therefore, in most cases, pancreatic cancer is diagnosed in its late stages (locally advanced non- metastatic or metastatic stage of the disease) when surgical resection and possibly curative treatment is not possible. It is generally assumed that only 10 % of cases are resectable at presentation, whereas 30- 40 % of patients are diagnosed at **the** ~~local~~ **locally** advanced / unresectable stage and 50- 60 % present with distant metastases. ~~7PDAC~~ **PDAC** Clinical Unmet Need and Market Opportunity PDAC is **currently** ~~one of~~ the ~~most fatal~~ **3rd leading cause of** ~~cancers~~ **cancer** ~~, accounting for~~ **- related deaths in the United States and** the 4th ~~highest~~ **leading** cause of cancer- ~~associated~~ **related** deaths in ~~the US and~~ the European Union **and it is projected to become the second leading cause of cancer- related deaths in the United States before 2030** . Despite significant research efforts, minimal progress has been achieved to date. The five- year overall survival rate is < 10 % and has not substantially improved over the last 30 years. Surgery is the only treatment that offers the prospect of long term- survival; however, the 5- year survival for the limited number of patients in whom resection is possible remains low (20 – 30 %). Patients with advanced disease are managed with chemotherapy. In recent years, the combination of gemcitabine with albumin- bound paclitaxel (GA), and the combination of folic acid, 5- fluorouracil, irinotecan and oxaliplatin (FOLFIRINOX) have emerged as the standard of care. ~~More recently~~ **In 2024** , liposomal irinotecan **(ONIVYDE ®)** , **which was previously** approved for second line PDAC in combination with fluorouracil and leucovorin, ~~has shown potential~~ **was approved in the United States and Europe** as first line therapy **for metastatic PDAC** when administered along with **oxaliplatin** 5- FU and **leucovorin (** ~~other~~ -- **the** ~~chemotherapies~~ **NALIRIFOX regimen)** . However, the results are still very poor and new therapeutic interventions are needed. The increase is particularly evident in younger people ~~and several studies anticipate that pancreatic cancer is expected to become the second leading cause of cancer- related death in the United States by 2030~~ . The rising incidence of pancreatic cancer and its current economic burden place increased pressure to improve outcomes for patients. In May 2011, the Committee for Orphan Medicinal Products (“ COMP ”) from the European Medicines Agency (“ EMA ”) recommended granting Orphan Medicinal Product Designation to VCN- 01 for the treatment of pancreatic cancer and in June 2011, the European Commission confirmed the designation under Regulation (“ EC ”) No 141 / 2000 of the European Parliament and of the Council. In June 2023, the FDA granted Orphan Drug **designation to VCN- 01 for the treatment of pancreatic cancer. In May 2024, the FDA granted Fast Track** designation to VCN- 01 for the treatment of pancreatic cancer. Phase 1a / Proof of Concept Trial of VCN- 01 by intratumoral administration in PDAC In September 2019, VCN presented a poster at the European Society for Molecular Oncology (“ ESMO ”) annual meeting describing initial mechanism of action data from a multicenter, Phase 1 dose escalation study of intratumoral (“ IT ”) VCN- 01 administered to pancreatic cancer patients in combination with standard doses / schedules of either gemcitabine or nab- paclitaxel plus gemcitabine (NCT02045589). The study was conducted at three hospitals in Spain and 8 patients with confirmed histologic diagnosis of unresectable PDAC amenable to endoscopic ultrasound guided (“ EUS ”) injection were treated with 3 injections (~~coincident~~ -- **coincide** with 1st day of the chemotherapy cycles) at two different dose levels of VCN- 01 (six patients had metastatic disease and two had locally advanced disease). The treatment regimen was generally well- tolerated ~~; however~~ **. VCN- 01- related adverse events were dose- dependent and mainly consisted of asthenia (6 patients)** , ~~one~~ **fever (4 patients), and transaminase increases (3 patients). One** patient died from severe **intra-** ~~intraabdominal~~ ----- **abdominal** fluid collection that was considered to be related to VCN- 01 treatment. Evaluation of virus pharmacokinetics and PH20 levels in serum were consistent with strong virus replication in the tumors. This was supported by the presence of viral particles in tumor cells as assessed in paired tumor biopsies collected before and after treatment. Tumor stiffness was reduced in all VCN- 01- injected lesions as measured by elastography. Disease stabilization of injected lesions was observed in 5 out of 6 patients although subsequent tumor progression was observed in most of the patients due to the appearance of new lesions or growth of distant, non- injected, metastatic lesions. This study provided encouraging mechanism of action data for VCN- 01; however, intratumoral injection did not appear to deliver sufficiently high VCN- 01 levels for effective delivery to non- injected tumors.

We believe these results supported the evaluation of the safety / tolerability and potential efficacy of VCN- 01 via intravenous administration in combination with chemotherapy and / or immunotherapies for the treatment of advanced PDAC. The results of this study were published in the Journal for Immunotherapy of Cancer. 2021 Nov; 9 (11): e003254. doi: 10. 1136 / jitc- 2021- 003254. ~~Phase~~ **8Phase** 1 Trial of intravenous VCN- 01 with or without nab- paclitaxel plus gemcitabine in patients with solid tumors and PDACIn March 2022, we announced the peer- reviewed publication of a Phase 1, multicenter, open- label, dose- escalation study investigating the safety, tolerability and biodistribution of intravenous VCN- 01 oncolytic adenovirus with or without standard- of- care (SoC) chemotherapy (gemcitabine / nab- paclitaxel) in patients with advanced solid tumors (NCT02045602). The data, published in the Journal for ImmunoTherapy of Cancer, suggests that intravenous treatment with VCN- 01 is feasible and has **been well tolerated** ~~an acceptable safety profile~~, with encouraging biological and clinical activity. (Journal for Immunotherapy of Cancer 2022; 10: e003255. doi: 10. 1136 / jitc- 2021- 003255). Data from the publication had previously been presented, in part, in a poster at the ESMO 2019 annual meeting. The published study was a multicenter, open- label, dose- escalation phase I clinical trial of a single dose of intravenous VCN- 01 alone (Part I, 16 patients with advanced refractory solid tumors) or in combination with nab- paclitaxel plus gemcitabine (Part II and III; patients with pancreatic adenocarcinoma). In Part II, 12 patients received VCN- 01 dose concurrent with chemotherapy on day 1, whereas in Part III 14 additional patients received the dose of VCN- 01 seven days before chemotherapy. The recommended Phase 2 doses (RP2D) were determined to be 1x1013 viral particles (vp) / patient in Part I, 3. 3x1012 vp / patient in Part II and 1x1013 vp / patient in Part III. Based on its apparent safety profile and the absence of dose- limiting toxicities, 1x1013 vp / patient using sequential dosing schedule was selected for further clinical development. ~~8Pharmacokinetic~~ **Pharmacokinetic** data showed dose linearity, as well as relevant VCN- 01 exposure. Analysis of VCN- 01 clearance in patients enrolled in Part II did not show significant differences with respect to patients receiving VCN- 01 as a single agent. VCN- 01 viral genomes were detected in tumor tissue in 5 out of 6 biopsies. A second viral peak in plasma and increased hyaluronidase serum levels suggested replication after intravenous injection in all patients. Increased levels of immune biomarkers (IFNγ, sLAG3, IL- 6, IL- 10) were found after VCN- 01 administration. In patients with pancreatic adenocarcinoma, the overall response rate (ORR) was 50 % for Part II and 50 % for Part III, as assessed by the investigators. Median progression free survival (PFS) for patients in Part III was 6. 7 months, and median overall survival (OS) was 13. 5 months. Eight patients (66. 7 %) survived more than 12 months. In addition, in April 2021, a subgroup analysis of patients at the RP2D (1. x1013 vp / patient followed by nab- paclitaxel plus gemcitabine one week later, n = 6) was conducted and showed an ORR of 83 %, with a median PFS of 6. 3 months and median OS of 20. 8 months. Some VCN- 01 treated patients appeared to benefit from late- onset responses. This form of delayed anti- tumor activity is not common with chemotherapy but is frequently observed with immunotherapies. We believe an immune mechanism of action associated with the oncolytic activity of VCN- 01 may be the underlying explanation. VCN- 01 appeared to convert the typically immunosuppressive tumor microenvironment of pancreatic adenocarcinomas into an enhanced inflammatory microenvironment (IDO, CD28, PD- 1, CTL signature up- regulation, and collagen formation) after treatment. Phase 2 Trial of intravenous VCN- 01 with or without nab- paclitaxel plus gemcitabine in patients with solid tumors and PDACIn January 2023, we dosed the first patients in VIRAGE, the Phase 2b randomized, open- label, placebo- controlled, multicenter clinical trial of systemically administered VCN- 01 in combination with standard- of- care (SoC) chemotherapy (gemcitabine / nab- paclitaxel) as a first line therapy for patients with newly- diagnosed metastatic pancreatic ductal adenocarcinoma. The study is **being** ~~expected to enroll 92 patients and be~~ conducted at approximately ~~25~~ **17** sites in the US and EU. Two doses of VCN- 01 are included in the treatment arm: the 1st dose is administered on day 1, then one week later 3 cycles of gemcitabine and nab- paclitaxel as standard of care is administered. The second VCN- 01 dose is administered 7 days before the 4th cycle of chemotherapy (approximately 90 days after the first VCN- 01 dose), followed by additional cycles of gemcitabine / nab- paclitaxel chemotherapy. Patient dosing was initiated in the U. S. in July 2023 and **on September 23, 2024, we announced that we have achieved our target patient enrollment of 92 evaluable patients in** the ~~fourteen~~ **VIRAGE Phase 2b clinical trial. Thirty- six** patients have received their second doses of intravenous VCN- 01, which were well tolerated and demonstrated the expected VCN- 01 ~~safety~~ **adverse event** profile. **Topline** ~~On February 7, 2024, we announced that the Independent Data~~ **data for** ~~Monitoring Committee (IDMC) recommended~~ the ~~continuation of enrollment as planned into~~ VIRAGE ~~, a multinational,~~ Phase 2b ~~, randomized, open- label, controlled~~ clinical trial **is anticipated** ~~evaluating VCN- 01 in combination with standard- of- care chemotherapy (gemcitabine / nab- paclitaxel) as a first- line therapy~~ for **Q2 2025** ~~patients with metastatic pancreatic ductal adenocarcinoma (PDAC)~~. ~~According to~~ **On January 30, 2024,** the **accumulated** ~~IDMC' s comprehensive assessment of~~ clinical data from patients enrolled across 6 sites open in the U. S. and 9 sites open in Spain **were reviewed by an Independent Data Monitoring Committee (IDMC). According to the IDMC' s assessment** , the ongoing Phase 2b trial ~~will continue~~ **continued** without any changes to the protocol. No safety concerns were raised based on the evaluation of data presented at the IDMC meeting. Intravenous VCN- 01 has been well tolerated and demonstrated a safety profile consistent with prior clinical trials. Importantly, no additional toxicities were observed in patients receiving a second dose of VCN- 01, providing the first clinical evidence of the feasibility of repeated systemic dosing. **9On May 10, 2024, we presented data demonstrating enhanced anti- tumor effects in human pancreatic cancer xenograft- bearing mice treated with lead product candidate VCN- 01 and liposomal irinotecan. These data support the potential synergy of VCN- 01 and first- line pancreatic cancer chemotherapy regimens. On May 23, 2024, we announced that the FDA granted Fast Track Designation (FTD) to lead clinical candidate VCN- 01 in combination with gemcitabine and nab- paclitaxel to improve progression- free survival and overall survival in patients with metastatic pancreatic adenocarcinoma. On June 1, 2024, we presented the design of** VIRAGE ~~remains~~ **trial in a poster at the American Society of Clinical Oncology (ASCO) Annual Meeting 2024 Congress held and in Chicago (Illinois) from May 31- June 4, 2024. The poster discussed the objectives, endpoints and key inclusion and exclusion criteria included in the trial protocol, together with the treatment schedule for each arm of the study. On December 5, 2024 we announced the outcomes of a Type D meeting with the FDA**

to obtain guidance on ~~track~~ **the design of a Phase 3 clinical study of VCN- 01 in combination with standard- of- care chemotherapy for the treatment of PDAC. FDA advised that the optimal path forward for the VCN- 01 PDAC program is** to **conduct a stand- alone Phase 3 study of VCN- 01 with gemcitabine / nab- paclitaxel. The FDA provided general agreement with our proposed design for a Phase 3 clinical study and indicated that inclusion of additional standard- of- care chemotherapy for PDAC was not necessary as it would** ~~complete~~ **complicate** ~~enrollment in~~ the ~~first half~~ **study design and analysis. The FDA meeting also highlighted the FDA' s preferences regarding certain statistical elements** of **confirmatory clinical studies, including methods for sample size estimation and the study population (s) used for data analysisOn February 4th,** ~~2024~~ **2025 , we received Scientific Advice from the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) on the design of a Phase 3 clinical study of VCN- 01 in combination with standard- of- care chemotherapy for the treatment of metastatic PDAC. Consistent with feedback from the FDA, CHMP advised that a marketing authorization application (MAA) for VCN- 01 in metastatic PDAC could be supported by positive results from a randomized, controlled, stand- alone Phase 3 study comparing VCN- 01 combined with gemcitabine / nab- paclitaxel to gemcitabine / nab- paclitaxel standard- of- care alone. The Scientific Advice also included CHMP suggestions regarding the study populations, inclusion / exclusion criteria, randomization and blinding, priority endpoints, and proposed statistical strategies for data analysis. An additional note from the EMA Committee for Orphan Medicinal Products (COMP) noted that the potential benefit of VCN- 01 with gemcitabine / nab- paclitaxel in a Phase 3 trial will be compared with the therapeutic effects of the other approved standard- of- care chemotherapies (FOLFIRINOX, NALIRIFOX) when considering maintenance of the Orphan Medicinal Product status of VCN- 01 at the time of an MAA** . Retinoblastoma Retinoblastoma is a tumor that originates in the retina and it is the most common type of eye cancer in children. It occurs in approximately 1 / 14, 000- 1 / 18, 000 live newborns and accounts for 15 % of the tumors in the pediatric population < 1 year old. The average age of pediatric patients at diagnosis is 2, and it rarely occurs in children older than 6. In the US, retinoblastoma shows an incidence rate of 3. 3 per 1, 000, 000 with only about 200 to 300 children diagnosed per year according to the American Cancer Society. Bilateral retinoblastoma (Rb1 germinal mutation) represents 25- 35 % of the cases while unilateral retinoblastoma (sporadic mutation) accounts for 65- 75 %. While retinoblastoma is a highly curable disease in the US, with a current disease- free survival rate of > 95 %, the clinical challenge for those who treat retinoblastoma is to preserve life and to prevent the loss of an eye, blindness and other serious effects of treatment that reduce the patient' s life span or the quality of life. In addition, children with retinoblastoma have been more likely to lose their eye and die of metastatic disease in low- resource countries. ~~9Current~~ **Current** treatments are not without significant morbidity, which may include visual impairment and severe cosmetic deformity secondary to enucleation and / or irradiation of the orbital region. The use of intravenous chemotherapy and more recently intra- arterial and intravitreal chemotherapy have resulted in a significantly greater number of eyes preserved with fewer long- term effects compared to past treatments such as external radiation therapy. However, allowing patients with advanced intraocular disease to be treated conservatively, led to the appearance of a subgroup of patients with advanced intraocular disease who relapsed after an initial response. Most of these cases include those patients who present gross vitreous or subretinal seeding. Once the aforementioned treatments are exhausted, these patients rarely manage to preserve the eyes and vision and must be enucleated. The ocular preservation rate of these eyes with advanced disease is still less than 50 %. In February 2022, the FDA granted Orphan Drug designation to VCN- 01 for the treatment of retinoblastoma. ~~Phase~~ **10Phase** 1 Trial of intravitreal VCN- 01 in patients with retinoblastomaDuring the third quarter of 2017, VCN entered into a Clinical Trial Agreement with Hospital Sant Joan de Déu (Barcelona, Spain) to conduct an investigator sponsored Phase 1 clinical study evaluating the safety and tolerability of two intravitreal injections of VCN- 01 in patients with intraocular retinoblastoma refractory to systemic, intra- arterial or intravitreal chemotherapy, or radiotherapy, in whom enucleation was the only recommended treatment (NCT03284268). Patients received two ~~doses~~ **intravitreal injections** of VCN- 01 ~~injected~~ **,** 14 days apart ~~using~~ **, at** a dose ~~escalation regimen. At this time, the dose- escalation phase~~ of **either** ~~the study has already been completed in 6 patients distributed in two cohorts (~~2 x 109 vp / eye **(n = 1** ~~and 2 x 1010 vp / eye~~) **or** ~~. VCN- 01 was well tolerated to date after intravitreal administration, although some degree of intravitreal inflammation and associated turbidity were observed. Inflammation has been managed and potential turbidity minimized with local and systemic administration of anti- inflammatory drugs. VCN- 01 does not appear to change the retinal function, and selective VCN- 01 replication in retinoblastoma cells has been observed by immunohistochemical analysis. Replication within retinoblastoma tumors over time was detected and VCN- 01 reduced the number of vitreous seeds in 4 out of 5 patients treated at~~ 2 x 1010 vp / eye (n = ~~5~~ **8**). The **clinical database for the study** ~~investigator has reported that one patient treated with VCN- 01 has had a complete regression lasting more than 30 months. This Phase 1 trial with VCN- 01~~ has now ~~completed enrollment~~ **been locked and the clinical study report is being prepared. On April 23, 2024, we announced positive topline data from this study, with agreement by the study Monitoring Committee that the study had a positive outcome. VCN- 01 was well tolerated after intravitreal administration at the 2 doses and the most frequently reported treatment- related adverse events were Grade 1 or 2. There were no dose limiting toxicities and no ocular or systemic toxicities equal to or greater than Grade 3 during the evaluation period. ● Some degree of ocular inflammation and associated turbidity was observed after VCN- 01 injection. Inflammation was managed, and vitreous haze improved in some cases, by local and systemic administration of anti- inflammatory drugs. ● VCN- 01 does not appear to change the retinal function, and selective VCN- 01 replication in retinoblastoma cells has been observed by immunohistochemical analysis. ● Replication within retinoblastoma tumors over time was detected ● Intravitreal VCN- 01 demonstrated promising antitumor activity: oFour patients presented a response characterized by unequivocal improvement in vitreous seed density. oEye enucleation was avoided in 3 patients to date, one of whom has retained their eye after 4 years of follow- up. Per the terms of the clinical trial agreement, the determination by the study Monitoring Committee that the study had a positive outcome means we received** ~~and~~ **an** ~~a total~~ **exclusive, worldwide technology license, and related patents from Hospital**

Sant Joan de Déu for the treatment of ~~nine~~ **pediatric patients with advanced retinoblastoma and we will pay to Hospital Sant Joan de Déu the amount of three hundred twenty thousand, two hundred and sixty five Euros** (~~9 €~~ **320, 265**) ~~patients been treated. This~~ **or approximately $ 334, 000, upon receipt by us of the final clinical** study **report** ~~is expected to complete patient follow- up in Q1 2024~~ . A pre- **Investigational New Drug (“** IND **”)** meeting with the FDA was held on December 19, 2023 to discuss the path forward for VCN- 01 as an adjunct to chemotherapy in pediatric patients with advanced retinoblastoma. The FDA provided some guidance on the potential endpoints and patient population for an advanced clinical trial and encouraged submission of a formal protocol under a US IND in order to provide more detailed commentary. ~~Dr. Angel Montero- Carcaboso presented new data~~ **On July 30, 2024, we received notice** from the ~~study~~ **FDA that we had been granted Rare Pediatric Drug Designation (RPDD)** for ~~which~~ **VCN- 01 for** ~~he~~ **the treatment of retinoblastoma. The FDA grants RPDD for rare diseases (fewer than 200, 000 affected persons in the United States) that are serious and life- threatening and primarily affect children ages 18 years or younger. If a Biologics License Application for VCN- 01 for the treatment of retinoblastoma** is **approved by** the **FDA by September 30** ~~lead investigator atan oral presentation entitled “ Topotecan enhances oncolytic adenovirus infection~~ , ~~replication and antitumor activity in~~ **2026, we may be eligible to receive a Priority Review Voucher. Previously, the FDA granted orphan drug designation to VCN- 01 for treatment of** retinoblastoma **. On** ~~, ” at Fundació Sant Joan de Déu at the SIOP 2022 Congress of the International Society of Pediatric Oncology, that was held in Barcelona, Spain from September 28-~~ October ~~1~~ **11** , ~~2022~~ **2024 ,** ~~. The new data from~~ the ~~study~~ **European Commission adopted the European Medicines Agency (EMA) recommendation to grant Orphan Medicinal Product Designation to VCN- 01** for ~~which Dr. Angel Montero- Carcaboso is the lead investigator further support evaluation of VCN- 01, an oncolytic adenovirus expressing hyaluronidase, and topotecan for~~ the treatment of ~~refractory retinoblastoma~~ **retinoblastoma11VCN** ~~. Key data and conclusions showcased in the SIOP presentation include: ● VCN- 01 treatment in combination with topotecan, but not with carboplatin or melphalan, significantly increased VCN- 01 infection and replication in retinoblastoma cells (p = 0. 0007) in vitro. ● In athymic mice engrafted with human retinoblastomas, topotecan administered systemically after intratumoral VCN- 01 increased viral genome replication and the number of VCN- 01 infected cells when compared to administration of VCN- 01 alone (p = 0. 0002). ● Sequential administration of intratumoral VCN- 01 followed by systemic topotecan significantly increased median ocular survival, compared to VCN- 01 alone (p = 0. 0364). 10VCN~~ - 01 in combination with Immunomodulatory therapeuticsBased on the clinical and pre- clinical data described below, we believe that the administration of VCN- 01, can elicit an anti- tumor immune response that could potentiate the effects of VCN- 01 and co- administered therapeutics. Biopsies from the Phase 1 trial of PDAC patients administered intravenous VCN- 01 demonstrated lymphocyte (CD8) infiltration and modulated levels of immune markers in tumors, including an induction of the PD1 / PD- L1 expression in tumor tissue from some of the patients. Preclinical experiments demonstrated that VCN- 01 significantly increased extravasation of an anti- PD- L1 antibody into subcutaneous xenograft tumors compared to non- treated (PBS) tumors and also that PH20 hyaluronidase improves the ingress of T- cells in animal models. **We believe** ~~Thus, we hypothesize~~ that the administration of VCN- 01 into the tumor ~~will~~ **may** help to overcome the observed resistance to PD- L1 checkpoint inhibitors and to mesothelin- directed CAR- T cells. Phase 1 Trial of intravenous VCN- 01 in Combination with Durvalumab in Subjects with Recurrent / Metastatic SCCHN In February 2019, VCN entered into a Clinical Trial Agreement with Catalan Institute of Oncology (ICO) (Spain) to conduct an investigator sponsored Phase 1 clinical study to evaluate the safety, tolerability and RP2D of a single intravenous injection of VCN- 01 combined with durvalumab in two administration regimens: VCN- 01 concomitantly with durvalumab, or sequentially with durvalumab starting two weeks after VCN- 01 administration (NCT03799744). The study is also designed to evaluate whether VCN- 01 treatment can re- sensitize PD- (l)- 1 refractory tumors to subsequent anti- PD- L1 therapy. Durvalumab is a human monoclonal antibody (mAb) of the immunoglobulin G (IgG) 1 kappa subclass that inhibits binding of PD- L1. It is marketed as IMFINZI ® by AstraZeneca / MedImmune, who supplied the product for its use in the clinical study. This Phase I trial is a multicenter, open label, dose escalation study in patients with histologically confirmed head and neck squamous cell carcinoma from specific sites: oral cavity, oropharynx, larynx or hypopharynx that is recurrent / metastatic (R / M) and not amenable to curative therapy by surgery or radiation. In addition, all patients should have undergone prior exposure to anti- PD- (L) 1 and progressed. Patients are entered at each dose level, according to a planned dose escalation schedule. The treatment is a single intravenous VCN- 01 dose combined with concomitant intravenous durvalumab (MEDI4736) 1500 mg Q4W (Arm I) or durvalumab starting two weeks after VCN- 01 administration (“ sequential schedule ”; Arm II). Patient recruitment into Arm I and Arm II was performed concurrently. Intravenous VCN- 01 was administered to each patient only once during the trial at the VCN- 01 dose level to which they were randomized. Durvalumab was administered Q4W until disease progression, unacceptable toxicity, withdrawal of consent, or another discontinuation criterion. Patient recruitment into the study was completed in February 2022 with a total of 18 patients enrolled. On September ~~05~~ **5** , 2022 we announced a presentation of initial data from this study in a poster at the European Society for Medical Oncology (ESMO) Congress. The poster reported that treatment with VCN- 01 had an acceptable safety profile when administered with durvalumab in the sequential schedule and the most common treatment- related adverse events were dose- dependent and reversible pyrexia, flu- like symptoms and increases in liver transaminases. Sustained blood levels of VCN- 01 viral genomes and increased serum hyaluronidase levels were maintained for over six weeks and analysis of tumor samples showed an increase in CD8 T cells (a marker of tumor inflammation); upregulation of PD- L1; and downregulation of matrix- related pathways after VCN- 01 administration. The ~~last patients in this~~ study ~~are currently~~ **has been completed and the clinical study report is** being **prepared** ~~followed for overall survival and patent samples are being analyzed to evaluate potential VCN- 01 pharmacodynamic effects~~ . On October 16, 2023, we presented additional data from this study in a poster at the European Society for Medical Oncology (ESMO) 2023 Congress held virtually and in Madrid, ~~Spian~~ **Spain** from October 20- 24, 2023. Key data and conclusions featured in the ESMO presentation include: ● 20 patients were enrolled with a median of 4 prior lines of therapy, from which six in the concomitant (CS) (single dose of VCN- 01 in combination with durvalumab on day 1) and 12 in the

sequential (SS) (single dose of VCN- 01 on day- 14 and durvalumab on day 1) were evaluable for response. ● In the CS cohort at the 3. 3 × 1012 viral particles (vp) dose, overall survival (OS) was 10. 4 months. ● In the SS cohort at the 3. 3 × 1012vp dose OS was 15. 5 months, whereas in the SS cohort at the 1 × 1013 vp dose OS was 17. 3 months. ● 11 patients (61. 1 %) were alive > 12 months (2 in CS; 5 in SS at 3. 3 × 1012vp, 4 in SS at 1 × 1013 vp). ● In spite of the advanced stage of the disease, and a global objective response rate for the trial of 5. 5 %, most of the patients appeared to benefit from subsequent treatment, with 2 patients showing complete responses to palliative chemotherapy and at least one patient still alive 4 years after entering the study. ● Biological activity: Patients showed VCN- 01 replication and increased serum hyaluronidase levels were maintained for over six weeks. ~~11~~ ● Observed an increase in CD8 T cells, a marker of tumor inflammation and an upregulation of PD- L1 in tumors. **12** ● Increase of PDL1- **combined positive score (** CPS ~~(~~**;** 16 / 21; p = 0. 013) and CD8 T- cells (12 / 21; p = 0. 007) from baseline were found in tumor biopsies. ● There was a ~~statistical~~ **statistically** significant correlation between OS observed in patients and CPS on day 8 (p = 0. 005). Phase 1 Trial evaluating the safety and feasibility of huCART- meso cells when given in combination with VCN- 01In July 2021, VCN entered into a Clinical Trial Agreement with the University of Pennsylvania (Philadelphia) to conduct an investigator sponsored Phase 1 clinical study to evaluate the safety, tolerability and feasibility of intravenous administration of VCN- 01 in combination with lentiviral transduced huCART- meso cells (developed by the laboratory of Dr. Carl June) in patients with histologically confirmed unresectable or metastatic pancreatic adenocarcinoma and serous epithelial ovarian cancer (NCT05057715). This is a Phase I study evaluating the combination of VCN- 01 when given in combination with huCART- meso cells in a dose- escalation design in two cohorts (N = 3- 6), where patients receive VCN- 01 as a single IV infusion (at 3. 3x1012 or 1x1013 vp) on Day 0, followed by a single dose of 5x107 huCART- meso cells on Day 14 via IV infusion. huCART- meso cells are modified T- cells targeting the mesothelin antigen, which is frequently expressed in multiple tumor types, particularly in pancreatic and ovarian cancers. Dr. June' s previous clinical studies have shown that huCART- meso cells encounter significant challenges in the tumor microenvironment, including immunosuppressive cells and soluble factors as well as metabolic restrictions. Initial VCN- 01 clinical data from the studies described above suggest that administration of VCN- 01 may increase tumor immunogenicity and improve access of the huCART- meso cells to tumor cells. This Phase I study will evaluate the safety and tolerability of the VCN- 01 huCART- meso cell combination and test the hypothesis that administration of VCN- 01 may enhance the potential antitumor effects of the co- administered huCART- meso cells. On July 8, 2022, we were notified that the first patient to be dosed with VCN- 01 had passed the safety evaluation period in this study. ~~The study is on- going.~~ On June 22, 2023, at their Cellicon Valley conference, and again at the Society for Immunotherapy of Cancer (SITC) meeting in San Diego, CA on November ~~03~~ **3** , 2023, and the International Oncolytic Virotherapy Conference (IOVC2023) in Calgary on November 13 2023, University of Pennsylvania investigators presented preliminary clinical safety and pharmacokinetic data from this study highlighting the feasibility of administering VCN- 01 in sequence with huCART- meso cells in pancreatic and ovarian cancer patients. VCN- 01 persistence was suggestive of tumor infection and active replication. The peak and duration of huCART- meso T cells in the peripheral blood as well as duration of stable disease in evaluable patients showed encouraging trends. **On October 16, 2024, at the 2024 Advancing Gene Therapy and Cell Therapies for Cancer conference by the American Society for Gene and Cell Therapy in Philadelphia, University of Pennsylvania investigators presented results from the Phase 1 trial of huCART- meso cells administered in combination with VCN- 01 in patients with pancreatic and serous epithetlial ovarian cancer. Safety was in line with expectations from monotherapy studies and 3. 3x1012 was defined as the dose for further development.** The **Cmax** ~~study will test higher doses~~ of **huCART- meso cells showed some signs of enhancement in patients previously infused with** VCN- 01 ~~and will interrogate~~ **. 66. 6 % (4 out of 6) patients with measurable disease receiving huCART- meso after VCN- 01 showed** tumor ~~biopsies to gain further insights. The results will inform~~ **shrinkage, indicating a promising trend in disease stabilization in patients receiving huCART- meso** and ~~guide optimization of~~ **VCN- 01 compared to either agent alone. On November 19, 2024 we were notified by the investigators that** ~~the~~ **they would not continue with the present clinical trial, instead preferring to focus on advancement of a next- generation mesothelin- specific CAR- T. This new CAR- T could potentially be evaluated in** combination ~~of CAR T cells~~ with ~~oncolytic virus~~ **VCN- 01 in a future clinical trial** . Phase 1 Trial evaluating the intravenous administration of VCN- 01 in patients prior to surgical resection of high- grade brain tumorsIn the second quarter of 2021, VCN entered into a Clinical Trial Agreement with the University of Leeds (UK) to sponsor a proof- of- concept Phase 1 clinical study to evaluate whether intravenously administered VCN- 01 can cross the blood- brain barrier and infect the target brain tumor. This is an open- label, non- randomized, single center study of VCN- 01 given intravenously at a dose of 1x1013 virus particles to patients prior to planned surgery for recurrent high- grade primary or metastatic brain tumors. We believe that the intravenous delivery of anti- cancer therapy to brain tumors, if effective, may enable the treatment of systemically disseminated brain metastases and may allow for reduction in the need to use neurosurgery to administer the drugs. This study aims to assess the presence of VCN- 01 within the resected surgical specimen after systemic VCN- 01 delivery and determine the safety of intravenous VCN- 01 in patients with recurrent high- grade glioma or brain metastases. By confirming the presence of VCN- 01 in high grade brain tumors following intravenous delivery, this study may pave the way for larger trials to study VCN- 01 efficacy, both as a monotherapy and in combination with PD- 1 / PD- L1 blockade. This trial has already received approval from Medicines & Healthcare Products Regulatory Agency (MHRA) from UK Government. On January 9, 2023, we issued a press release announcing that the first patient was dosed in this study and recruitment is on- going. ~~12Our~~ **13Our** Current Gastrointestinal (GI) and Microbiome- Focused PipelineOur SYN- 004 (ribaxamase) and SYN- 020 clinical programs are focused on the gastrointestinal tract (GI) and the gut microbiome, which is home to billions of microbial species and composed of a natural balance of both " good " beneficial species and potentially " bad " pathogenic species. When the natural balance or normal function of these microbial species is disrupted, a person' s health can be compromised. All of our programs are supported by our ~~growing~~ **established** intellectual property portfolio **and prosecution of existing applications** . We are ~~maintaining and building~~ **exploring value creation options for** our **SYN- 004** ~~patent portfolio through: filing new~~

~~patent applications; prosecuting existing applications;~~ and **SYN- 020 assets, including out-** licensing **or partnering** ~~and acquiring new patents and patent applications~~. SYN- 004 (ribaxamase) — Prevention of antibiotic- mediated microbiome damage, thereby preventing overgrowth and infection by pathogenic organisms such as Clostridioides difficile infection (CDI) and vancomycin resistant Enterococci (VRE), and reducing the incidence and severity of acute graft- versus- host disease (aGVHD) in allogeneic HCT recipientsSYN- 004 (ribaxamase) is a proprietary oral capsule prophylactic therapy designed to degrade certain IV beta- lactam antibiotics excreted into the GI tract and thereby maintain the natural balance of the gut microbiome. Preventing beta- lactam damage to the gut microbiome has a range of potential therapeutic outcomes, including prevention of CDI, suppression of the overgrowth of pathogenic species (particularly antimicrobial- resistant organisms) and potentially reducing the incidence and / or severity of aGVHD in allogeneic hematopoietic cell transplant (HCT) patients. SYN- 004 (ribaxamase) 75 mg capsules are intended to be administered orally while patients are administered certain IV beta- lactam antibiotics. The capsule dosage form is designed to release the SYN- 004 (ribaxamase) enzyme into proximal small intestine, where it has been shown to degrade beta- lactam antibiotics in the GI tract without altering systemic antibiotic levels. Beta- lactam antibiotics are a mainstay in hospital infection management and include the commonly used penicillin and cephalosporin classes of antibiotics. Clostridioides difficile InfectionClostridioides difficile (formerly known as Clostridium difficile and often called C. difficile or CDI) is a leading type of hospital acquired infection and is frequently associated with IV beta- lactam antibiotic treatment. The Centers for Disease Control and Prevention (CDC) identified C. difficile as an " urgent public health threat, " particularly given its resistance to many drugs used to treat other infections. CDI is a major unintended risk associated with the prophylactic or therapeutic use of IV antibiotics, which may adversely alter the natural balance of microflora that normally protect the GI tract, leading to C. difficile overgrowth and infection. Other risk factors for CDI include hospitalization, prolonged length of stay (estimated at 7 days), underlying illness, and immune- compromising conditions including the administration of chemotherapy and advanced age. ~~According to a paper published in BMC Infectious Diseases (Desai K et al. BMC Infect Dis. 2016; 16: 303) the economic cost of CDI was approximately $ 5. 4 billion in 2016 ($ 4. 7 billion in healthcare settings; $ 725 million in the community) in the U. S., mostly due to hospitalizations.~~ Limitations of Current Treatments and Market OpportunityCDI is a widespread and often drug resistant infectious disease. Approximately 20 % of patients who have been diagnosed with CDI experience a recurrence of CDI within one to three months. Furthermore, controlling the spread of CDI has proven challenging, as the C. difficile spores are easily transferred to patients via normal contact with healthcare personnel and with inanimate objects. There is currently no vaccine or approved product for the prevention of primary (incident) CDI. The current standard of care for primary CDI, as outlined by the Infectious Disease Society of America (IDSA), is to treat with powerful antibiotics such as fidaxomicin or vancomycin. Prolonged use of fidaxomicin and vancomycin has been shown to further exacerbate damage to the gut microbiome, leading to increased risk of CDI recurrence as well as the emergence of pathogenic and antimicrobial- resistant (AMR) organisms, such as vancomycin- resistant enterococci (VRE). AMR is a serious global threat and one which world leaders have begun to take action against. According to the European Society of Clinical Microbiology and Infections Disease (ECCMID), failure to address AMR could lead to a potential " antibiotic Armageddon ", resulting in 10 million deaths worldwide by 2050 and may cost as much as $ 100 trillion in worldwide economic output. **The Centers for** ~~13According to a paper published in BMC Infectious Diseases~~ **Disease Control estimates the crude overall incidence rate of CDI in the United states to be 121. 2 cases per 100** , ~~" Epidemiological~~ **000 persons (approximately 500, 000 patients) with a higher rate of community associated compared to healthcare associated infection (CDC Emerging Infections Program Healthcare- Associated Infections – Community Interface Report Clostridioides difficile Infection Surveillance, 2022. https: / / www. cdc. gov / healthcare- associated- infections / media / pdfs / 2022- CDI- Report- 508. pdf) The overall incidence of CDI has declined since 2015 as better infection prevention practices** and **antimicrobial stewardship have decreased the number of healthcare associated acquired infections (Guh et al. N Engl J Med. 382: 1320); however, the** economic **and social** ~~burden~~ **burdens** of ~~Clostridium difficile~~ **CDI remain high. CDI infections are estimated to cost $ 5 billion per annum** in the United States ~~: estimates from a modeling approach ".~~ **, primarily due to increased hospitalization and hospital length of stay, while mortality rates as high as 39 % have been reported for patients with multiple episods of recurrent CDI** (~~Desai~~ **Feuerstadt** et ~~.~~al. ~~,~~BMC Infect Dis ~~16~~ **23** : ~~303~~ **132; Malone et al. Antimicrob Steward Healthc Epidemiol 3: e17.**) ~~, it is estimated that approximately 606, 000 patients are infected with C. difficile annually in the U. S., and it has been reported that approximately 44, 500 deaths are attributable to CDI- associated complications each year. According to IMS Health Incorporated *, in 2016, the potential addressable market for SYN- 004 (ribaxamase) included approximately 227 million doses of intravenous Penicillin and Cephalosporin antibiotics which were administered in the United States and which may contribute to the onset of CDI. Additional data derived from IMS Health Incorporated states that in 2016, the worldwide market for SYN- 004 (ribaxamase)- addressable intravenous beta- lactam antibiotics was approximately 7. 5 billion doses, which may represent a multi- billion- dollar market opportunity for us~~. If approved, SYN- 004 (ribaxamase) would be the first therapeutic intervention indicated to prevent the onset of antibiotic- mediated primary CDI. ~~Phase~~ **14Phase** 1a and 1b Clinical Trial Pharmacokinetic DataIn March 2015, we reported supportive pharmacokinetic data from a Phase 1a clinical trial, which suggested that SYN- 004 (ribaxamase) should have no effect on the IV antibiotic in the bloodstream, allowing the antibiotic to fight the primary infection. In February 2015, we reported supportive topline results from a subsequent Phase 1b clinical trial of escalating doses of oral SYN- 004 (ribaxamase), with no safety or tolerability issues reported at dose levels and dosing regimens that were equivalent to or exceeded those expected to be studied in subsequent clinical trials. The Phase 1a (40 participants) and 1b (24 participants) clinical trials of SYN- 004 (ribaxamase) were initiated in December 2014. Two Phase 2a Clinical Trials: Topline ResultsIn December 2015, we reported supportive topline results from our first Phase 2a clinical trial of SYN- 004 (ribaxamase, NCT02419001). The study demonstrated that SYN- 004 (ribaxamase) successfully degraded IV ceftriaxone in the chyme of ten participants with ileostomies without affecting the levels of ceftriaxone in the bloodstream. In May 2016, we reported supportive topline results from a second Phase 2a clinical

trial of SYN- 004 (ribaxamase) in 14 healthy participants with functioning ileostomies administered IV ceftriaxone with and without oral SYN- 004 (ribaxamase) (NCT02473640). This second study demonstrated that the 150 mg dose of SYN- 004 (ribaxamase), both alone and in the presence of the proton pump inhibitor (PPI), esomeprazole, degraded ceftriaxone excreted into the chyme resulting in ceftriaxone levels that were low or not- detectable. Ceftriaxone plasma concentrations in participants of the second study were not altered by SYN- 004 (ribaxamase) in the presence or absence of an oral PPI, suggesting limited drug- drug interactions. The 150 mg dose of SYN- 004 (ribaxamase) was well tolerated by all participants in this clinical trial. Phase 2b Proof of Concept Clinical Trial Design & ResultsIn September 2015, we initiated a multicenter, randomized, placebo- controlled Phase 2b proof- of- concept clinical study in 412 patients (206 per group; NCT02563106). On January 5, 2017, we announced positive topline data from our Phase 2b proof- of- concept clinical trial intended to evaluate the ability of SYN- 004 (ribaxamase) to prevent CDI, CDAD (C. difficile- associated diarrhea) and AAD (antibiotic- associated diarrhea) in patients hospitalized for a lower respiratory tract infection and receiving IV ceftriaxone. Results from this study demonstrated that SYN- 004 (ribaxamase) achieved its primary endpoint of significantly reducing CDI. Preliminary analysis of the data indicated seven confirmed cases of CDI in the placebo group compared to two cases in the SYN- 004 (ribaxamase) treatment group. Patients receiving SYN- 004 (ribaxamase) achieved a 71. 4 % relative risk reduction (p- value = 0. 045) in CDI rates compared to patients receiving placebo. SYN- 004 (ribaxamase) treated patients also demonstrated a significant reduction in new colonization by vancomycin- resistant enterococci (VRE) compared to placebo (p- value = 0. 002). Results from this trial also demonstrated that patients administered ribaxamase in conjunction with IV- ceftriaxone demonstrated comparable cure rates (approximately 94 %) for the treatment of primary infection compared to the placebo group. Results from this trial also demonstrated that the percentage of subjects reporting at least one treatment emergent adverse event (TEAE) was similar between SYN- 004 (ribaxamase) and placebo treatment groups (40. 8 % vs 44. 2 %). Adverse events reported during this trial were comparable between treatment and placebo arms. Serious adverse events (SAEs) in the treatment arm, including fatal AEs, which exceeded those in the placebo arm, were not considered drug- related by investigators at the clinical sites, or by an independent third- party, each of whom determined SAEs were attributable to disparities in the underlying health and comorbidities between the groups. * This information is an estimate derived from the use of information under license from the following IMS Health Incorporated information service: IMS Health Analytics for the full year 2016. IMS expressly reserves all rights, including rights of copying, distribution, and republication. ~~14On~~ **On** October 6, 2016 we were awarded a government contract in the amount of $ 521, 014 by the CDC' s Broad Agency Announcement (BAA) 2016- N- 17812 to examine changes in the gut resistome of patients in our Phase 2b clinical study. Data generated under this contract are consistent with SYN- 004' s (ribaxamase) mode of action of preserving the normal gut flora by degrading ceftriaxone in the upper GI tract of study participants treated with SYN- 004 (ribaxamase). The data further demonstrated that SYN- 004 (ribaxamase) significantly reduced the loss of microbial diversity, reduced overgrowth of opportunistically pathogenic species (such as VRE), and reduced the emergence of antimicrobial resistance (AMR) genes caused by ceftriaxone treatment in SYN- 004 (ribaxamase) treated patients compared to placebo. ~~Future~~ **15Future** Potential Regulatory Strategy for Prevention of Primary CDIOn November 21, 2018, we announced results from our End- of- Phase 2 meeting with the FDA during which key elements of a Phase 3 clinical program were confirmed. Pursuant to the meeting, the FDA proposed criteria for Phase 3 clinical efficacy and safety which, if achieved, may support submission for marketing approval of SYN- 004 (ribaxamase) on the basis of a single Phase 3 clinical trial. The proposed SYN- 004 (ribaxamase) Phase 3 clinical program entails a single, global, event- driven clinical trial with a fixed maximum number of approximately 4, 000 patients for total enrollment and evaluates the potential efficacy and safety of ribaxamase in a broad patient population by enrolling patients with a variety of underlying infections treated with a range of IV beta- lactam antibiotics. The proposed Phase 3 clinical trial incorporates co- primary safety and efficacy endpoints (mortality and the reduction in the incidence of CDI at one month after the last drug dose in the SYN- 004 (ribaxamase) treatment group versus placebo, respectively). We expect the clinical development costs to complete this trial to be in excess of $ 80 million and anticipate initiating the Phase 3 clinical program only after securing additional potential financing via a strategic partnership. Acute Graft- Versus- Host- Disease in Allogeneic Hematopoietic Cell Transplant (allogeneic HCT) Recipients & SYN- 004 (ribaxamase) In parallel with our clinical and regulatory efforts, we completed a Health Economics Outcomes Research (HEOR) study, which was conducted to generate key insights on how we can expect Health Care Practitioners, or HCPs, to evaluate patient access for SYN- 004 (ribaxamase) while also providing a framework for potential reimbursement strategies. After evaluating findings from the study, we believe that there is significant potential value in exploring the development of SYN- 004 (ribaxamase) in a narrower patient population where the incidence of the disease endpoint is high and the clinical development may be less costly. We believe allogeneic hematopoietic cell transplant (HCT) recipients, who have a very high risk of CDI, VRE colonization and potentially fatal bacteremia, and acute- graft- vs- host disease (aGVHD), represent such a patient population. Published literature has demonstrated a strong association between these adverse outcomes and microbiome damage caused by IV beta- lactam antibiotics in these patients. Approximately 80- 90 % of HCT recipients receive IV beta- lactam antibiotics to treat febrile neutropenia. Penicillins and cephalosporins are first- line therapies in the USA and EU, whereas carbapenems are first- line in China. Antibiotic- mediated damage to the gut microbiome is strongly associated with GVHD, bloodstream infections, VRE bacteremia, transplant relapse, and increased mortality in HCT recipients, raising concern over the spectrum of antibiotics used during HCT. CDI occurs in up to 31 % of HCT patients and is associated with GVHD and increased mortality. aGVHD occurs in 30- 60 % of allogeneic HCT recipients and is recognized as a primary contributor to morbidity and mortality in this patient population. The most recent available data indicate approximately 8, 000 reported allogeneic HCT procedures each year in the USA, 19, 800 procedures in Europe, 12, 700 in China, and 3, 500 in Japan. First- line treatments for aGVHD fail in more than 50 % of patients and 2- year survival in patients with steroid refractory aGVHD is only 20 %. At least one U. S. study found allogeneic HCT recipients who developed aGVHD had 3- times higher in- hospital mortality and almost 2- fold higher median hospital costs than patients who did not develop aGVHD. It has been reported that

in- patient costs for allogeneic HCT in the USA range from $ 180, 000- $ 300, 000 depending on the disease severity. In 2014, all- cause costs for allogeneic HCT in the USA were greater than $ 600, 000 per patient (up to 12 months post- transplant). VRE infection is a persistent problem in HCT patients and VRE colonization after HCT has been associated with decreased patient survival. Phase 1b / 2a Clinical Study in Allogeneic HCT RecipientsIn August 2019, we entered into a Clinical Trial Agreement (CTA) with the Washington University School of Medicine (Washington University) to conduct a Phase 1b / 2a clinical trial of SYN- 004 (ribaxamase). Under the terms of this agreement, we serve as the sponsor of the study and supply SYN- 004 (ribaxamase). Dr. Erik R. Dubberke, Professor of Medicine and Clinical Director, Transplant Infectious Diseases at Washington University and a member of the SYN- 004 (ribaxamase) steering committee serves as the principal investigator of the clinical trial in collaboration with his Washington University colleague Dr. Mark A. Schroeder, Associate Professor of Medicine, Division of Oncology, Bone Marrow Transplantation and Leukemia. ~~15The~~ **16The** Phase 1b / 2a clinical trial **was** ~~will comprise~~ a single center, randomized, double- blinded, placebo- controlled clinical trial of oral SYN- 004 (ribaxamase) in up to 36 evaluable adult allogeneic HCT recipients. The goal of this study is to evaluate the safety, tolerability and potential absorption into the systemic circulation (if any) of oral SYN- 004 (ribaxamase; 150 mg four times daily) administered to allogeneic HCT recipients who receive an IV carbapenem or beta- lactam antibiotic to treat fever. Study participants **were** ~~will be~~ enrolled into three sequential cohorts administered a different study- assigned IV antibiotic. Each cohort seeks to complete eight evaluable participants treated with SYN- 004 (ribaxamase) and four evaluable participants treated with placebo. Safety and pharmacokinetic data for each cohort will be reviewed by an independent Data and Safety Monitoring Committee, which will make a recommendation on whether to proceed to the next IV antibiotic cohort. The study will also evaluate potential protective effects of SYN- 004 on the gut microbiome as well as generate preliminary information on potential therapeutic benefits and patient outcomes of SYN- 004 in allogeneic HCT recipients. To date, we have completed **2** ~~the first~~ of 3 cohorts (~~Cohort~~ **Cohorts** 1 **and 2**) in this study ~~, which enrolled 19 patients who received at least 1 dose of study drug (SYN- 004 or Placebo randomized 2: 1). Sixteen patients received at least one dose of intravenous (IV) meropenem and 12 of these patients completed sufficient doses of IV meropenem to be evaluable towards the study endpoints~~ . On September 27, 2022, we issued a press release announcing positive outcomes from the Data and Safety Monitoring Committee (“ DSMC ”) review of results from the first Cohort and their recommendation that the study may proceed to enroll Cohort 2 in which study drug (SYN- 004 or Placebo) is administered in combination with the IV beta- lactam antibiotic piperacillin / tazobactam. On ~~November 3, 2022 we announced the first patient had been dosed in Cohort 2. Patient dosing is on- going and if enrollment proceeds on the current schedule, we may be positioned to announce data readouts for the second cohort during the first half of 2024 and the third cohort during the first half of 2025. On~~ February 16, 2023 and April 13, 2023 **,** we announced the presentation of safety and pharmacokinetic data from Cohort 1 of the Phase 1b / 2a Clinical Trial of SYN- 004 (ribaxamase) in allogeneic hematopoietic cell transplant recipients at the 2023 Tandem Meetings: Transplantation & Cellular Therapy Meetings of ASTCT and CIBMTR and at the European Congress of Clinical Microbiology & Infectious Diseases (ECCMID) **,** respectively **. On October 3, 2024, we announced a positive outcome from the DSMC review of results from the second Cohort of our Phase 1b / 2a randomized, double- blinded, placebo- controlled clinical trial of SYN- 004 (ribaxamase) in allogeneic hematopoietic cell transplant (“ HCT ”) recipients for the prevention of acute graft- versus- host- disease. Based on a review of the safety and pharmacokinetic data, the DSMC recommended that the study may proceed to enroll Cohort 3 in which study drug (SYN- 004 or Placebo) will be administered in combination with the IV beta- lactam antibiotic cefepime. Based upon our current available funding and our focus on our clinical development of VCN- 01 we do not anticipate that enrollment for the third cohort will commence unless we obtain grant funding, or find a licensee or partner for the SYN- 004 development program** . SYN- 020 — Oral Intestinal Alkaline Phosphatase (IAP) SYN **-** 020 is a quality- controlled, recombinant version of bovine Intestinal Alkaline Phosphatase (IAP) produced under cGMP conditions and formulated for oral delivery. The published literature indicates that IAP functions to diminish GI and systemic inflammation, tighten the gut barrier to diminish “ leaky gut, ” diminish fat absorption, and promote a healthy microbiome. Despite its broad therapeutic potential, a key hurdle to commercialization has been the high cost of IAP manufacture which is commercially available for as much as $ 10, 000 per gram. We believe we have developed technologies to traverse this hurdle and now have the ability to produce more than 3 grams per liter of SYN- 020 and anticipate a cost of roughly a few hundred dollars per gram at commercial scale. Based on the known mechanisms as well as our own supporting animal model data, we intended to initially develop SYN- 020 to mitigate the intestinal damage caused by radiation therapy that is routinely used to treat pelvic cancers. While we believe SYN- 020 may play a pivotal role in addressing acute and long- term complications associated with radiation exposure to the GI tract, we have also begun planning for potential development of SYN- 020 in large market indications with significant unmet medical needs. Such indications include celiac disease, non- alcoholic fatty liver disease (“ NAFLD ”), and indications to treat and prevent metabolic and inflammatory disorders associated with aging ~~, which are supported by our collaboration with Massachusetts General Hospital (“ MGH ”)~~ . On June 30, 2020, we submitted an IND application to the FDA in support of an initial indication for the treatment of radiation enteropathy secondary to pelvic cancer therapy. On July 30, 2020, we announced that we received a study- may- proceed letter from the FDA to conduct a Phase 1a single- ascending- dose (“ SAD ”) study in healthy volunteers designed to evaluate SYN- 020 for safety, tolerability and pharmacokinetic parameters (NCT04815993) ~~. On April 1, 2021, we announced that enrollment had commenced in the Phase 1 SAD clinical trial of SYN- 020~~ . On June 29, 2021, we announced that enrollment, patient dosing and observation had been completed in the Phase 1, open- label, SAD study of SYN- 020. The SAD study enrolled 6 healthy adult volunteers into each of four cohorts with SYN- 020 given orally as single doses ranging from 5 mg to 150 mg. The data demonstrated that SYN- 020 maintained a favorable safety profile, was well tolerated at all dose levels, and no adverse events were attributed to the study drug. No serious adverse events were reported. ~~16During~~ **17During** the third quarter of 2021 we initiated a Phase 1 clinical study evaluating multiple ascending doses (“ MAD ”) of SYN- 020 (NCT05045833) ~~. On October 21, 2021 we announced that patient enrollment, dosing, and observation~~

~~commenced in the Phase 1 MAD study of SYN- 020~~ . The placebo- controlled, blinded study enrolled 32 healthy adult volunteers into four cohorts with SYN- 020 administered orally in doses ranging from 5 mg to 75 mg twice daily for 14 days with a follow- up evaluation at day 35. Each cohort included six subjects who received SYN- 020 and two who received placebo. On May 10, 2022, we announced positive safety data from the Phase 1 MAD study demonstrating that SYN- 020 maintained a favorable safety profile and was well- tolerated across all dose levels. There were a few treatment- related adverse events, and all were mild (grade 1) and resolved without medical intervention. The most common adverse event, constipation, occurred in three out of 24 subjects in the treatment arm and in one out of eight subjects in the placebo arm. No adverse event led to discontinuation of the study drug and there were no serious adverse events. Additionally, fecal SYN- 020 analyses verified intestinal bioavailability while plasma levels of SYN- 020 were below the limit of quantitation in all samples at all timepoints verifying that SYN- 020 was not absorbed into the systemic circulation. During the second quarter of 2020, we announced that we entered into an agreement with Massachusetts General Hospital (" MGH ") granting us an option for an exclusive license to intellectual property and technology related to the use of IAP to maintain GI and microbiome health, diminish systemic inflammation, and treat age- related diseases ~~. During the second quarter of 2021~~ , **which** ~~we announced an amendment to our~~ option **was later amended** ~~for an exclusive license agreement with MGH to include intellectual property and technology related to the use of SYN- 020 to inhibit~~ liver fibrosis in select diseases, including NAFLD. **The option expired unexercised on July 1** ~~Research published by a team of investigators led by Richard Hodin~~ , **2024** ~~MD, Chief of the Massachusetts General Hospital Division of General and Gastrointestinal Surgery and Professor of Surgery, Harvard Medical School, evaluated long- term oral supplementation of IAP, including SYN- 020, in mice. Dr. Hodin' s research demonstrated that IAP administration, starting at 10 months of age, slowed the microbiome changes, gut- barrier dysfunction, and gastrointestinal and systemic inflammation that normally accompany aging. Additionally, the IAP administration resulted in improved metabolic profiles in the aged mice, diminished frailty, and extended lifespan. Under the terms of the agreement, we are granted exclusive rights to negotiate a worldwide license with MGH to commercially develop SYN- 020 to treat and prevent metabolic and inflammatory diseases associated with aging. If executed, we plan to use this license in the advancement of an expanded clinical development program for SYN- 020~~ . The Phase 1 data from our SAD and MAD studies are intended to support the development of SYN- 020 in multiple clinical indications including radiation enteritis, NAFLD, celiac disease, and **diseases associated** ~~indications supported by our collaboration~~ with **aging** ~~Massachusetts General Hospital~~ . With our transition to an oncology focused Company, we are exploring strategic opportunities to enable advancement of this potentially valuable asset. Future Potential Regulatory Strategy for Prevention of Primary CDIAs part of our strategic transformation into an oncology focused company, we are exploring value creation options for our SYN- 004 and SYN- 020 assets, including out-licensing or partnering. ~~Research Programs~~~~VCN~~ **VCN- 01 Topoisomerase InhibitorsOn May 10, 2024, we presented non-clinical describing enhanced anti- tumor effects in human pancreatic cancer xenograft- bearing mice treated with lead product candidate VCN- 01 and liposomal irinotecan in a poster at the 27th American Society of Gene and Cell Therapy (ASGCT) 2024 Congress held in Baltimore (Maryland) from May 7** - 11 **, 2024. These data support the potential synergy of VCN- 01 and additional first- line pancreatic cancer chemotherapy regimens FOLFIRINOX and NALIRIFOX. Key finding reported in the poster include: ● The combination of VCN- 01 topoisomerase I (topo1) inhibitors, such as liposomal irinotecan, has a tolerable toxicity profile and may improve efficacy in the treatment of human pancreatic cancer. ● Viral protein expression was increased in human pancreatic cancer cell lines when they were exposed to topo1 inhibiting chemotherapeutics, irinotecan, its active metabolite, SN- 38, and topotecan. ● Synergy of VCN- 01 plus liposomal irinotecan was observed in animals bearing subcutaneous human pancreatic tumors. oIn human pancreatic mouse xenograft models, treatment with VCN- 01 at a dose of 4x1010 vp or liposomal irinotecan alone (at both the 10 mg / kg and 5 mg / kg doses) resulted in significant tumor growth inhibition compared to saline. oCombination therapy with VCN- 01 liposomal irinotecan at either dose displayed significantly reduced tumor growth compared to each treatment alone. oqPCR analyses performed on tumors collected at end of study confirmed the presence of viral genomes, indicating ongoing transcriptional activity of VCN- 01, which is consistent with viral replication for several days after administration. 18VCN- X Next Generation OVs and** Albumin Shield ™ ~~Technology~~~~VCN~~ **TechnologyIn parallel with VCN- 01 clinical development, we are developing next- generation oncolytic adenoviruses (termed VCN- X) with novel therapeutic payloads and structural modifications to increase tumor cell killing and improve systemic virus pharmacokinetics. Preclinical proof- of- concept has been established with VCN** - 11 **, which** ~~is a novel virus that we believe has the potential to extend our OV platform. VCN- 11~~ has been engineered to contain all of the features of VCN- 01 as well as an additional modification to include an albumin binding domain (ABD) in the virus capsid. The virus capsid is the target for neutralizing antibodies (NAbs) that are generated by the host immune system to destroy circulating viruses. The presence of an **ABD** ~~albumin binding domain~~ , however, blocks the binding of most neutralizing antibodies, which allows the virus to reach the tumor following intravenous administration. This " Albumin Shield " works because human blood contains a large amount of albumin to coat the ~~VCN~~ **ABD** - ~~11~~ **containing** virus. Importantly, this coating of albumin appears to be displaced after the virus reaches tumor cells to infect them. In pre- clinical mouse studies to test the functionality of the " ~~albumin~~ **Albumin** ~~shield~~ **Shield** ", mice pre- immunized with virus are able to completely neutralize an unmodified OV because they have a large concentration of neutralizing antibodies in their blood. By contrast, viruses ~~containing the albumin binding domain~~ such as VCN- 11 **that contain the ABD** are not neutralized and retain their ability to infect and destroy tumor cells. We believe ~~these~~ -- **the** results **with VCN- 11** support the **application** ~~further development~~ of **the Albumin Shield technology in our** VCN- ~~11~~ **X program to advance treatments** for tumors in which rapid multi- dosing may be beneficial. In ~~the second quarter of 2020, VCN had several interactions with Spanish regulatory authorities (AEMPS) to agree on the design of the non-clinical GLP toxicology and biodistribution studies that are required to support a first- in- human clinical trial for VCN- 11. 17In~~ March 2021, preclinical data obtained with VCN- 11 was published (J Control Release. 2021 Apr 10; 332: 517- 528), showing

that ~~VCN~~ **the ABD** - ~~11~~ **containing virus** induced 450 times more cytotoxicity in tumor cells than in normal cells. ~~VCN~~ **Hyaluronidase production was** confirmed ~~VCN- 11 hyaluronidase production~~ by measuring the activity of the PH20 enzyme with a hyaluronic acid- degradation assay, and by measuring PH20 activity in VCN- 11 infected tumors in vivo. ~~VCN~~ **The ABD** - ~~11~~ **containing virus** evaded NAbs from different sources and tumor levels of **virus** ~~VCN- 11~~ were demonstrated in the presence of high levels of NAbs in vivo, whereas the control virus without ABD was neutralized. VCN- 11 showed a low toxicity profile in athymic nude mice and Syrian hamsters, allowing treatments with high doses and fractionated administrations without major toxicities (up to 1. 2x1011vp / mouse and 7. 5x1011vp / hamster). ~~VCN- 11 increased~~ ALT levels **were increased** on day 3 within an acceptable range that returned to normal levels by day 9. Fractionated intravenous administration of ~~VCN~~ **the ABD** - ~~11~~ **containing virus** (splitting the dose into two portions administered 4 h apart) appeared to improve **virus** ~~VCN- 11~~ circulation kinetics and increase tumor levels. ~~VCN- 11 showed antitumor~~ **Antitumor** efficacy **was observed** in the presence of NAbs against Ad5 and ~~itself~~ **the ABD- containing virus** . In May 2022, we presented **data** ~~on VCN- 11~~ at the 25th Annual Meeting of the American Society of Gene & Cell Therapy (ASGCT). The presentation included preclinical results showcasing the potential of ~~VCN- 11~~ **the Albumin Shield Technology** to ~~balance safety, with no major toxicities observed, and~~ effectively target tumors after intravenous re- administration, even in the presence of high level NAbs **, with no major toxicities observed** . Our internal **VCN- X** discovery programs are currently evaluating new oncolytic viruses ~~derived from VCN- 11~~ that **contain the Albumin Shield technology and** may expand the potential efficacy of ~~Albumin Shield~~ **Theriva' s oncolytic** viruses ~~. SYN- 006, SYN- 007, other oncolytic virusTo date, our Research programs that have been directed to the development of GI acting products have generated preclinical proof- of- concept with two potential pipeline products (SYN- 006 and SYN- 007) designed to expand the utility of our beta- lactamase strategy. SYN- 007 is a specially formulated version of SYN- 004 (ribaxamase) designed to be used with orally administered beta- lactam antibiotics to protect the gut microbiome from antibiotic- mediated dysbiosis. SYN- 006 is a carbapenemase designed to degrade intravenous (IV) carbapenem antibiotics within the GI tract to maintain the natural balance of the gut microbiome for the prevention of CDI, overgrowth of pathogenic organisms and the emergence of antimicrobial resistance (AMR). The scope of our research is expanding to include development of new oncolytic virus products with alternative modes of action, and may include oncology applications of our existing products such as SYN- 006 and SYN- 007~~ . Intellectual PropertyAll of our programs are supported by growing patent estates. In total, Theriva Biologics has over ~~130~~ **175** U. S. and foreign patents and over ~~65~~ **60** U. S. and foreign patents pending. VCN, through assignment or exclusive licenses, controls over ~~40~~ **50** U. S. and foreign patents and over 15 U. S. and foreign patents pending. The SYN- 004 (ribaxamase) program is supported by **intellectual property (“** IP **”)** that is assigned to Theriva Biologics, namely U. S. and foreign patents (in most major markets, e. g. Europe (including Germany, Great Britain and France), Japan, China and Canada, among others) and U. S. and foreign patents pending (in most major markets, e. g. Europe (including Germany, Great Britain and France), Japan, China and Canada, among others). For instance, U. S. Patent Nos. 8, 894, 994 and 9, 587, 234, which include claims to compositions of matter and pharmaceutical compositions of beta- lactamases, including SYN- 004 (ribaxamase), have patent terms to at least 2031. Further, U. S. Patent 9, 301, 995 and 9, 301, 996, both of which will expire in at least 2031, cover various uses of beta- lactamases, including SYN- 004 (ribaxamase), in protecting the microbiome, and U. S. Patent Nos. 9, 290, 754, 9, 376, 673, 9, 404, 103, 9, 464, 280, and 9, 695, 409 which will expire in at least 2035, covers further beta- lactamase compositions of matter related to SYN- 004 (ribaxamase). The SYN- 020 (oral intestinal alkaline phosphatase (IAP)) program is supported by IP that is assigned to Theriva Biologics, namely U. S. and foreign patents and patent applications (in many major markets, e. g. Europe, China, Japan, Korea, Canada, and Australia). These patents and patent applications, which cover various formulations, medical uses and manufacture of SYN- 020, are expected to expire in 2038- 2040, without taking potential patent term extensions or patent term adjustment into account. ~~18The~~ **19The** VCN- 01 and **Albumin Shield** ~~VCN- 11~~ programs are supported by U. S. and foreign patents and patent applications that are assigned to VCN or exclusively licensed from Fundació Privada Institut d' Investigacio Biomedica de Bellvitge (IDIBELL), Institut Catala d' Oncologia (ICO), and Hospital Sant Joan de Déu in Barcelona. The patents and patent applications include U. S. patents and foreign patents (in most major markets, e. g. Europe, China, Japan, Korea, Canada, Israel, Mexico, Russia, and Australia) and U. S. and foreign patents pending (in most major markets, e. g. Europe, China, Korea, Canada, Mexico, and India). The patents and patent applications cover compositions of matter and pharmaceutical compositions of oncolytic adenoviruses and various medical uses of the same. For instance, U. S. Patent No. 10, 316, 065, which expires in 2030 without taking potential patent term extensions or patent term adjustment into account, provides composition of matter and pharmaceutical composition coverage for a genus of engineered oncolytic adenovirus suitable for the treatment of solid tumors. Other patents and patent applications, if granted, will provide protection to 2037 without taking potential patent term extensions or patent term adjustment into account. Our goal is to (i) obtain, maintain, and enforce patent protection for our products, formulations, processes, methods, and other proprietary technologies, (ii) preserve our trade secrets, and (iii) operate without infringing on the proprietary rights of other parties worldwide. We seek, where appropriate, the broadest intellectual property protection for product candidates, proprietary information, and proprietary technology through a combination of contractual arrangements and patents. Acquisition of VCN Biosciences, S. L. (now known as Theriva Biologics, S. L.) On March 10, 2022, we completed our acquisition (the “ VCN Acquisition ”) of all the outstanding shares of VCN (the “ VCN Shares ”) from the shareholders of VCN pursuant to the terms of the Share Purchase Agreement (“ Purchase Agreement ”) that we entered into with VCN and the shareholders of VCN Biosciences, S. L. (the “ Sellers ”) on December 14, 2021. Upon consummation of the Acquisition, VCN became our wholly owned subsidiary. As consideration for the purchase of the VCN Shares of capital stock, we paid $ 4, 700, 000 (the “ Closing Cash Consideration ”) to Grifols Innovation and New Technologies Limited (“ Grifols ”), the owner of approximately 86 % of the equity of VCN, and issued to the remaining Sellers 2, 639, 530 shares of our common stock, $ 0. 001 par value (the “ Closing Shares ”), representing 19. 99 % of the outstanding shares of our common stock on December 14, 2021, the date of the Purchase Agreement. As additional consideration for the purchase of the VCN Shares held by Grifols, we also

agreed to make the following milestone payments to Grifols: Milestone PaymentsUS $ 3MM upon VCN- 01 US IND Safe to Proceed pancreatic ductal adenocarcinoma (“ PDAC ”, or other first indication), which payment was made in Q4 2022 upon attaining the milestoneUS $ 2. 75MM upon VCN- 01 US IND Safe to Proceed – retinoblastoma (“ RB ”, or other second indication) US $ 3. 25MM upon VCN- 01 US first patient dosed – PDAC (or other first indication) after receipt of VCN- 01 US IND Safe to Proceed for PDAC being informed, which payment was made in Q4 2023 upon attaining the milestoneUS $ 3. 25MM upon VCN- 01 US first patient dosed – RB (or other second indication) after receipt of VCN- 01 US IND Safe to Proceed for RB being informedUS $ 6MM upon VCN- 01 US Phase 2 trial meets the primary endpoint or if a Phase 2 trial is not conducted and only a Phase 3 trial is conducted then upon a Phase 3 being initiated – PDAC (or other first indication) US $ 8MM upon VCN- 01 Pivotal Trial meeting the primary endpoint or upon **Submission of a Biologics License Application (‘** BLA ~~Submission~~ **”)** – RB (or other second indication) US $ 12MM upon VCN- 01 US Phase 3 trial meeting the primary endpoint or upon BLA Submission – PDAC (or other first indication) US $ 16MM upon VCN- 01 BLA Approval – PDAC (or other first indication) US $ 16MM upon VCN- 01 BLA Approval – RB (or other second indication) ~~Pursuant~~ **20Pursuant** to the Purchase Agreement, at the Closing we assumed $ 2, 400, 000 of liabilities of VCN, which includes certain loans from the Spanish Government and the Catalan Government Agency. ~~19The~~ -- **The** Purchase Agreement contains customary representations, warranties and covenants of the Sellers and us. Subject to certain customary limitations, the Sellers have agreed to indemnify us and our officers and directors against certain losses related to, among other things, breaches of their representations and warranties, certain specified liabilities and the failure to perform covenants or obligations under the Purchase Agreement. Effective November 15, 2022, as part of our corporate rebranding, VCN changed its name to Theriva Biologics S. L. without other changes to its corporate structure ~~. Theriva is a clinical- stage biopharmaceutical company developing new oncolytic adenoviruses for the treatment of cancer. Theriva’ s lead product candidate, VCN- 01, is being studied in clinical trials for pancreatic cancer and retinoblastoma with additional investigator sponsored trials in indications including head and neck squamous cell carcinoma (HNSCC) serous epithelial ovarian cancer and brain tumors. VCN- 01 is designed to be administered systemically, intratumorally or intravitreally, either as a monotherapy or in combination with standard of care, to treat a wide variety of cancer indications. VCN- 01 is designed to replicate selectively and aggressively within tumor cells, and to degrade the tumor stroma barrier that serves as a significant physical and immunosuppressive barrier to cancer treatment. Degrading the tumor stroma has been shown to improve access to the tumor by the virus and additional therapies such as chemo- and immuno- therapies. Importantly, degrading the stroma exposes tumor antigens, turning “ cold ” tumors “ hot ” and enabling a sustained anti- tumor immune response. Theriva has the exclusive rights to four patent families for proprietary technologies, as well as technologies developed in collaboration with the Virotherapy Group of the Catalan Institute of Oncology (ICO- IDIBELL) and with Hospital Sant Joan de Deu (HSJD), with a number of additional patents pending~~ . Our Current CollaborationsIDIBELL Technology Transfer AgreementOn August 31, 2010, VCN entered into a Technology Transfer Agreement (the “ Technology Transfer Agreement ”) with the Bellvitge Biomedical Research Institute (“ IDIBELL ”) for the exclusive license of the right to use a Spanish patent number P200901201 titled “ Oncolytic adenoviruses for treating cancer ” which is co- owned by IDIBELL and Catalan Oncology Institute (“ ICO ”) for the term of the patent. The Technology Transfer Agreement provides that IDIBELL is entitled to a low single digit percentage royalty on the income collected by VCN from the utilization of products derived from the licensed technology, prior to applying any value- added tax, if any, and low single digit percentage royalty on other income received by VCN arising from the use of the licensed technology, including income related to sublicenses of the licensed technology to third parties and advance payments or payments made for goals that were met and / or services associated with the licensed technology. The Technology Transfer Agreement terminates upon the expiration of the patent rights and is subject to early termination by either party in the event of a breach by the other party of its obligations thereunder. In addition, IDIBELL has the right to revoke the license if VCN ceases business activities for a continuous year or ceases to utilize the technology subject of the Technology Transfer Agreement, uses the technology in violation of the principals of IDIBELL or ICO or stops maintaining the patent licensed under the Technology Transfer Agreement ICO Marketing LicenseOn May 16, 2009, VCN entered into a Contract to Grant a Marketing License (the “ ICO License Agreement ”) with the Catalan Institute of Oncology (the “ ICO ”) for a manufacturing and marketing license of a patent P200700665 titled “ Adenovirus with mutations in the area of endoplasmic retention of protein E3- 19k and their use in the treatment of cancer ” in connection with a sublicense identified therein. The validity period of the license granted is unlimited with the only applicable limit being the patent’ s own validity. The ICO License Agreement provides that the ICO is entitled to a royalty of low double digit percentage of the net value of the income from the concession of the identified sublicense and low double digit percentage on other lump sums received thereunder. VCN and its sublicensees have an obligation to use all diligent and commercially reasonable efforts for the exploitation of the patent, otherwise, ICO may proceed to recover the license. The ICO License terminates upon the expiration of the patent rights and is subject to early termination by either party in the event of a breach by the other party of its obligations thereunder. ~~20IDIBELL~~ **21IDIBELL** / ICO License AgreementOn March 4, 2016, VCN entered into a License Agreement (the “ IDIBELL / ICO License Agreement ”) with IDIBELL and the ICO, for the exclusive license of the right to use a family of patents whose priority application is European patent application EP 14 38 2162. 7 titled “ Adenovirus comprising an albumin- binding moiety ”. The License Agreement provides that IDIBELL and ICO, as licensors, are entitled to share a low single digit percentage royalty on the annual Net Sales (as defined in the IDIBELL / ICO License Agreement) collected by VCN from the utilization of products derived from the licensed technology and a royalty on sublicensing income received from the licensed technology at a rate of: low double digit percentage during the first 3 years following the effective date of the agreement, mid- single digit percentage during the term of 3 to 7 years following the effective date and low single digit percentage thereafter. The IDIBELL / ICO License Agreement also provides for certain fixed payments, including a payment 25 days following the date of concession of the licensed patent in a minimum of three European jurisdictions and a payment 25 days following the date of concession of an American patent derived from the licensed patent.

The IDIBELL / ICO License is for an indefinite term subject to early termination (i) by mutual agreement of the parties; (ii) by licensor in the event of at least two successive breaches or three alternate breaches calculated annually of the obligation to pay any consideration; (iii) by VCN at its discretion due to certain patent infringements of rights protected by the patents or due to the absence of protection of the patent in any countries in the territory which is worldwide or (iv) in the event of a breach by the other party of its obligations thereunder which are not remedied within thirty (30) days. In addition, the licensors have the right to revoke the IDIBELL / ICO License Agreement if VCN during a continuous period of two years abandons its research or development activities of the licensed patent or activities aimed at exploitation of the resulting products, VCN has undertaken no marketing whatsoever during the term of the IDIBELL / ICO License Agreement or uses the patent licensed for purposes other those as set forth in the IDIBELL / ICO License Agreement. ~~Saint~~ **Sant** Joan De Déu Collaboration and License AgreementOn February 15, 2016, VCN entered into a Collaboration Agreement to Conduct a Clinical Trial and Grant an Operating License (the " Collaboration and License Agreement ") with the ~~Saint~~ **Sant** Joan De Déu Hospital (the " Hospital ") and the ~~Saint~~ **Sant** Joan De Déu Foundation (the " Foundation ", and together with the Hospital, the " Institution ") regarding the conduct of a clinical trial to evaluate the safety and activity of VCN- 01 in patients with refractory retinoblastoma. The Collaboration and License Agreement provides that if the trial results are positive and VCN is interested in continuing with the development of VCN- 01 for the treatment of retinoblastoma; (a) the parties undertake to apply their best efforts to negotiate and, where appropriate, sign an agreement to collaborate in the development and execution of the following phases of the development of VCN- 01 for the treatment of retinoblastoma; (b) the Institution shall grant to VCN an exclusive, worldwide and indefinite license to use and exploit the trial results and their possible patents exclusively for the treatment of retinoblastoma; (c) VCN shall pay the Foundation five hundred thousand Euros (€ 500, 000), subject to reduction for any public and / or private economic aid that third parties may grant to the Institution for the conduct of the trial and / or any advance payments made by VCN before the end of the trial; (d) VCN shall pay the Foundation three hundred twenty thousand Euros (€ 320, 000) once following the trial results of a pivotal study, to be carried out by VCN, has been completed which allows it to obtain the marketing authorization of the product following from the results, which payment must be made within a maximum period of four (4) years from the date on which Institution has delivered the final report of the trial to VCN; and (e) the parties will use their best efforts to negotiate and, where appropriate, sign a product supply agreement in order that the Hospital can use VCN- 01 for compassionate use in the treatment of retinoblastoma. The Collaboration and License Agreement continues in force and effect until all obligations arising from the trial have been fulfilled, subject to early termination for a material breach by a party of any of their contractual and / or legal obligations, or, in the case of any other type of breach, when the breaching party has been asked in writing to remedy the breach and the breach is not cured within thirty (30) days from the date on which the written request was sent. ~~On~~ **Per the terms of the clinical trial agreement, the determination by the study Monitoring Committee that the study had a positive outcome means we will receive an exclusive, worldwide technology license, and related patents from Hospital Sant Joan de Déu for the treatment of pediatric patients with advanced retinoblastoma and we will pay to Hospital Sant Joan de Déu the amount of three hundred twenty thousand Euros (€ 320, 265) or approximately $ 334, 000, upon receipt by us of the final clinical study reportOn** November 1, 2023, VCN and Sant Joan de Déu- Barcelona Children' s Hospital entered into an agreement for an exclusive worldwide option to negotiate an exclusive license of certain Sant Joan de Deu intellectual property rights related to the use of VCN- 01 in combination with topoisomerase I inhibitor chemotherapies for the treatment of cancer. **This option was extended by amendment on November 18, 2024.** The collaboration builds on growing data that suggests coadministration of VCN- 01 with topoisomerase I inhibitors such as topotecan can enhance VCN- 01 replication and antitumor activity in preclinical cancer models. Combination of VCN- 01 with a topoisomerase I inhibitor is expected to provide a synergistic antitumor effect wherein a chemotherapy- mediated increase in tumor VCN- 01 levels may enable greater degradation of the tumor stroma, significantly increasing chemotherapy access and tumor destruction. ~~21Washington~~ **22Washington** University School of Medicine in St. Louis Clinical Trial AgreementOn August 7, 2019, we entered into a clinical trial agreement (" CTA ") with Washington University School of Medicine in St. Louis (" Washington University ") to conduct a Phase 1b / 2a single- center, randomized, double- blinded, placebo- controlled clinical trial designed to evaluate the safety, tolerability and pharmacokinetics of oral SYN- 004 (ribaxamase) in up to 36 adult allogeneic hematopoietic cell transplant (HCT) recipients (the " Study "). Under the terms of the CTA, we will serve as the sponsor of the Study and supply SYN- 004 (ribaxamase), as well as compensate Washington University for all research services to be provided in connection with the Study which is estimated to cost approximately $ 3, 200, 000. Dr. Erik R. Dubberke, Professor of Medicine and Clinical Director, Transplant Infectious Diseases at Washington University will serve as the principal investigator of the trial in collaboration with his Washington University colleague Dr. Mark A. Schroeder, Associate Professor of Medicine, Division of Oncology, Bone Marrow Transplantation and Leukemia. The CTA continues in effect until completion of all obligations under the CTA. Either party may terminate the CTA prior to completion of its obligations (i) if authorization of the study is withdrawn by the FDA; (ii) if the emergence of any adverse reaction or side effect with SYN- 004 (ribaxamase) administered in the Study is of such magnitude or incidence in the opinion of either party to support termination; or (iii) upon a breach of the terms of the CTA if the breaching party fails to cure the breach within 30 days after receipt of notice. We have the right to terminate the CTA (i) effective immediately if Washington University fails to perform the study in accordance with the terms of the protocol, the CTA or applicable laws or regulations or if Washington University or the principal investigator become debarred or (ii) upon 14 days written notice and Washington University has the right to terminate the CTA upon 14 days notice if the principal investigator becomes unable to perform or complete the Study and the parties have not, prior to the expiration of such fourteen (14) day period, agreed to an alternative principal investigator. **Based upon our current available funding** ~~Massachusetts General Hospital Exclusive Option License AgreementOn May 27, 2020, we entered into an~~ **and our focus on our** ~~agreement with Massachusetts General Hospital (" MGH ") granting us an option for an exclusive license to intellectual property and technology related to the use of intestinal alkaline phosphatase (" IAP ") to maintain gastrointestinal~~

(GI) and microbiome health, diminish systemic inflammation, and treat age- related diseases. If executed, we plan to use this license in the advancement of an expanded clinical development program for SYN- 020, our proprietary recombinant version of VCN bovine IAP currently in pre- 01 clinical development. Under the terms of the agreement, we are granted exclusive rights to negotiate a worldwide license with MGH to commercially develop SYN- 020 to treat and prevent metabolic and inflammatory diseases associated with aging. During the second quarter of 2021, we announced an amendment to our option for an exclusive license agreement with MGH to include intellectual property and technology related to the use of SYN- 020 to inhibit liver fibrosis in select diseases, including NAFLD. To date, we have not exercised the option. The University of Texas at Austin License Agreement and Sponsored Research AgreementOn December 19, 2012, we entered into a Patent License Agreement (the " Texas License Agreement ") with UT Austin for the exclusive license of the right to use, develop, manufacture, market and commercialize certain research and patents related to pertussis antibodies developed in the lab of Dr. Jennifer A. Maynard, Associate Professor of Chemical Engineering. In accordance with the terms of the Texas License Agreement we made the following payments to the UT Austin: a payment of past patent expenses, an annual payment of $ 50, 000 per year commencing on the effective date through December 31, 2014 and a $ 25, 000 payment on December 31, 2015. The Texas License Agreement also provides that UT Austin is entitled to milestone payments of $ 50, 000 upon commencement of Phase 1 Clinical Trials, $ 100, 000 upon commencement of Phase 3 Clinical Trials, $ 250, 000 upon NDA submission in the United States, $ 100, 000 upon European Medicines Agency approval and $ 100, 000 upon regulatory approval in an Asian country. In addition, the University is entitled to a running royalty upon Net Product Sales and Net Service Sales (as defined in the Texas License Agreement and currently projected to be 2037 (not accounting for possible extensions)). The License Agreement terminates upon the expiration of the patent rights (as defined in the Texas License Agreement); provided, however that the Texas License Agreement is subject to early termination by us in our discretion and by the University for a breach of the Texas License Agreement by us. 22In connection with the Texas License Agreement, we also entered into a Sponsored Research Agreement (the " Sponsored Research Agreement ") with the University pursuant to which the University will perform certain research work related to pertussis under the direction of Dr. Jennifer Maynard. All inventions conceived during such research shall be subject to the Texas License Agreement and we will obtain certain rights to patents and technology developed during the course of such research. We paid the University a fixed fee for the first year of $ 303, 287 and the second and third years of $ 316, 438 and $ 328, 758, respectively. The termination date of the Sponsored Research Agreement n was amended multiple times and Sponsored Research Agreement expired on January 17, 2023. Upon a termination or due to a breach by the University, we were only be responsible for all reasonable expenses that do not anticipate exceed the fixed annual amount and that enrollment are incurred by the University prior to the termination date for services performed prior to the third cohort will commence unless we obtain grant funding termination date. We have an issued U. S. patent and patents pending in the U. S. and internationally (e. g. Europe , or find a licensee or partner for the China, Japan, Australia, and China) on compositions and uses of SYN- 004 development program 005 that are co- owned by UT Austin and ourselves or licensed to us, and we have an issued U. S. patent and patent applications on other pertussis mAbs licensed from UT Austin . ManufacturingVCN- 01 & VCN- 11Our oncolytic virus platform viruses (e. g. VCN- 01, VCN- 11) are biologics that can be readily synthesized by processes that we have developed in collaboration with Contract and Development Manufacturing Organizations (CDMOs) such as Thermo Fisher, BioReliance, GenIBET, and others. We do not own or operate manufacturing facilities for the production of our product candidates, VCN- 01 and VCN- 11, but we do produce and test viruses and virus processes at our facilities in Spain. Our cell and virus seed stocks and master / working cell banks are used for current and future production. Our cells for manufacturing are approved by and licensed from US regulatory authorities. Clinical and commercial supplies will be manufactured in facilities and by processes that comply with the FDA and other regulatory agency requirements. We plan to rely on third parties to manufacture commercial quantities of products that we successfully develop through regulatory approval. We have contracted with CDMOs GenIbet and ThermoFisher to provide what we believe are adequate clinical supplies for our planned clinical trials. Our upstream and downstream processes for producing oncolytic viruses are well understood in the industry and use industry standard cell factories and single use bioreactors for manufacturing. All downstream purifications employ single- use columns and filters, and release testing is performed by third- party vendors using qualified or validated assays. Critical quality attributes and other product testing specifications for our clinical supplies are agreed to with regulatory authorities prior to release and use. We have previously encountered some delays in manufacturing due to the impact of COVID- 19 on the supply chain. The potential impact of similar supply chain issues from a future pandemic COVID- 19 resurgence or other pandemic disruption to global trade and supply chains , if any, on our on- going and future clinical trials is currently unknown. SYN 23SYN - 004 and SYN- 020Our product candidates SYN- 004 and SYN- 020 are biologics that can be readily synthesized by processes that we have developed; however, the manufacturing for our clinical programs, including SYN- 004 and SYN- 020 may require long lead times and has in the past been subject to COVID- 19 related global supply chain interruptions. We do not own or operate manufacturing facilities for the production of these product candidates for preclinical and clinical activities. We rely on third- party contract manufacturers, and in most cases only one third- party, to manufacture critical raw materials, drug substance and final drug product for our research, preclinical development and clinical trial activities. Commercial quantities of any drugs we seek to develop will have to be manufactured in facilities and by processes that comply with the FDA and other regulations, and we plan to rely on third parties to manufacture commercial quantities of products we successfully develop through FDA approval. Research and DevelopmentDuring the years ended December 31, 2024 and 2023 and 2022 , we incurred approximately $ 12. 0 million and $ 14. 3 million and $ 11. 7 million , respectively, in research and development expenses. 23Government -- Government RegulationIn the U. S., the formulation, manufacturing, packaging, storing, labeling, promotion, advertising, distribution and sale of our products are subject to regulation by various governmental agencies, including primarily the FDA. Our proposed activities may also be regulated by various agencies of the states, localities and foreign countries in which our proposed products may be manufactured, distributed and sold. The FDA, in particular, regulates

the formulation, manufacture and labeling of prescription drugs, such as those that we intend to distribute. FDA regulations require us and our suppliers to meet relevant cGMP regulations for the preparation, packing, labeling, and storage of all drugs. Any products manufactured or distributed by us pursuant to FDA approvals are subject to pervasive and continuing FDA regulation, including record- keeping requirements, reporting of adverse experiences, submitting periodic reports, drug sampling and distribution requirements, manufacturing or labeling changes, record- keeping requirements, and compliance with FDA promotion and advertising requirements. Drug manufacturers and their subcontractors are required to register their facilities with the FDA and state agencies, and are subject to periodic unannounced inspections for GMP compliance, imposing procedural and documentation requirements upon us and third- party manufacturers. Failure to comply with these regulations could result, among other things, in suspension of regulatory approval, recalls, suspension of production or injunctions, seizures, or civil or criminal sanctions. We cannot be certain that we or our present or future subcontractors will be able to comply with these regulations. The FDA regulates prescription drug labeling and promotion activities in the United States. The FDA actively enforces regulations prohibiting the marketing of products for unapproved uses. The FDA permits the promotion of drugs for unapproved uses in certain circumstances, subject to stringent requirements. We and our product candidates are subject to a variety of state laws and regulations which may hinder our ability to market our products. Whether or not FDA approval has been obtained, approval by foreign regulatory authorities must be obtained prior to commencing clinical trials, and sales and marketing efforts in those countries. These approval procedures vary in complexity from country to country, and the processes may be longer or shorter than that required for FDA approval. We may incur significant costs to comply with these laws and regulations now or in the future. The FDA, comparable foreign regulators and state and local pharmaceutical regulators impose substantial requirements upon clinical development, manufacture and marketing of pharmaceutical products. These and other entities regulate research and development and the testing, manufacture, quality control, safety, effectiveness, labeling, storage, record keeping, approval, advertising, and promotion of our products. The drug approval process required by the FDA under the Food, Drug, and Cosmetic Act **(the " FDCA ")** and Public Health Service Act **(the " PHS Act ")** (for biologics) generally involves: ● preclinical laboratory and animal tests; ● submission of an IND, prior to commencing human clinical trials; ● adequate and well- controlled human clinical trials to establish safety and efficacy for intended use; ● submission to the FDA of ~~an~~ **a new drug application (" NDA ")** or BLA; and **24** ● FDA review and approval of an NDA or BLA. The testing and approval process requires substantial time, effort, and financial resources, and we cannot be certain that any approval will be granted on a timely basis, if at all. OVs such as VCN- 01 are genetically modified organisms and their import and use are subject to additional review and approval by dedicated agencies in some countries where we propose to run clinical trials, including Spain and other European countries. Preclinical tests include laboratory evaluation of the product candidate, its chemistry, formulation and stability, and animal studies to assess potential safety and efficacy. Certain preclinical tests must be conducted in compliance with good laboratory practice regulations. Violations of these regulations can, in some cases, lead to invalidation of the studies, requiring them to be replicated. In some cases, long- term preclinical studies are conducted concurrently with clinical studies. ~~24We~~ **We** will submit the preclinical test results, together with manufacturing information and analytical data, to the FDA as part of an IND, which must become effective before we begin human clinical trials. The IND automatically becomes effective 30 days after filing, unless the FDA raises questions about conduct of the trials outlined in the IND and imposes a clinical hold, in which case, the IND sponsor and FDA must resolve the matters before clinical trials can begin. It is possible that our submission may not result in FDA authorization to commence clinical trials. The timing and requirements of IND review may differ from the FDA in other countries, potentially delaying study initiation at sites in those countries. Clinical trials must be supervised by qualified investigators in accordance with current good clinical practice (cGCP) regulations, which include informed consent requirements. Each study must be approved and monitored by the appropriate Institutional Review Boards (IRBs) or **Instituional** ~~ethics~~ **Ethics** ~~committees~~ **Committees** (~~ECs~~ **IECs**) which are periodically informed of the study' s progress, adverse events and changes in research. OVs such as VCN- 01 are genetically modified organisms and their use is also subject to review and approval by the Institutional Biosafety Committee (IBC) at each clinical trial site. Annual updates are submitted to the FDA and comparable foreign regulators (if required) with more frequent reporting if certain serious adverse events occur. Human clinical trials of drug candidates typically have three sequential phases that may overlap: Phase 1: The drug is initially tested in healthy human subjects or patients for safety, dosage tolerance, absorption, metabolism, distribution, and excretion. Phase 2: The drug is studied in a limited patient population to identify possible adverse effects and safety risks, determine efficacy for specific diseases and establish dosage tolerance and optimal dosage. Phase 3: When Phase 2 evaluations demonstrate that a dosage range is effective with an acceptable safety profile, Phase 3 trials to further evaluate dosage, clinical efficacy and safety, are undertaken in an expanded patient population, often at geographically dispersed sites. We cannot be certain that we will successfully complete Phase 1, Phase 2, or Phase 3 testing of our product candidates within any specific time period, if at all. Furthermore, the FDA or comparable foreign regulator, an IRB / ~~EC~~ **IEC** or the IND sponsor may suspend clinical trials at any time on various grounds, including a finding that subjects or patients are exposed to unacceptable health risk. Under the Pediatric Research Equity Act, we also must prepare, within 60 days of an End of Phase 2 meeting, a pediatric study plan or request for waiver or deferral of pediatric studies in the indication under development. Concurrent with these trials and studies, we also develop chemistry and physical characteristics data and finalize a manufacturing process in accordance with cGMP requirements. The manufacturing process must conform to consistency and quality standards, and we must develop methods for testing the quality, purity, and potency of the final products. Appropriate packaging is selected and tested, and chemistry stability studies are conducted to demonstrate that the product does not undergo unacceptable deterioration over its shelf- life. Results of the foregoing are submitted to the FDA as part of an NDA (or BLA in case of biologic products) for marketing and commercial shipment approval. The FDA reviews each NDA or BLA submitted and may request additional information. A 60- day period after the sponsor' s submission of an NDA or BLA is used by the FDA to determine whether the application is sufficiently complete to permit substantive review, in which case the application is

accepted for filing. The timing and requirements of NDA or BLA review may differ from the FDA in other countries, ~~Once~~ **25Once** the FDA accepts the NDA or BLA for filing, it begins its in- depth review. The FDA has substantial discretion in the approval process and may disagree with our interpretation of the data submitted or identify new concerns. The process may be significantly extended by requests for new information or clarification of information already submitted. As part of this review, the FDA may refer the application to an advisory committee, typically a panel of clinicians. Manufacturing establishments often are inspected prior to NDA or BLA approval to assure compliance with GMPs and with manufacturing commitments made in the application. Submission of an NDA or BLA with clinical data requires payment of a substantial fee. **The** ~~In return, the~~ FDA assigns a goal for review and decision on the application, in which the FDA may approve ~~or deny~~ the NDA or BLA ~~,~~ or issue a complete response letter outlining information needed to support approval, including a potential need for additional clinical data. Even if these data are submitted, the FDA may ultimately decide the NDA or BLA does not satisfy approval criteria. If the FDA approves the NDA or BLA, the product becomes available for marketing. Product approval may be withdrawn if regulatory compliance is not maintained or safety problems occur. The FDA may require post- marketing studies, also known as Phase 4 studies, as a condition of approval, and Risk Evaluation and Mitigation Strategies (REMS) requires surveillance programs to monitor approved products that have been commercialized. The agency has the power to require changes in labeling or prohibit further marketing based on the results of post- marketing surveillance. ~~25Satisfaction~~ -- **Satisfaction** of these and other regulatory requirements typically takes several years, and the actual time required may vary substantially based upon the type, complexity and novelty of the product. Government regulation may delay or prevent marketing of potential products for a considerable period of time and impose costly procedures on our activities. We cannot be certain that the FDA or other regulatory agencies will approve any of our products on a timely basis, if at all. Success in preclinical or early- stage clinical trials does not assure success in later- stage clinical trials. Data obtained from preclinical and clinical activities are not always conclusive and may be susceptible to varying interpretations that could delay, limit or prevent regulatory approval. Even if a product receives regulatory approval, the approval may be significantly limited to specific indications or uses. Even after regulatory approval is obtained, later discovery of previously unknown problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market. Delays in obtaining, or failures to obtain regulatory approvals would have a material adverse effect on our business. The FDA' s or comparable foreign regulatory agency may change their policies, and additional government regulations may be enacted which could prevent or delay regulatory approval of our potential products. Increased attention to the containment of health care costs worldwide could result in new government regulations materially adverse to our business. Public perception and sentiment regarding genetically modified organisms and / or viral therapies (including vaccines) can be highly variable and may impact legislation regarding the potential sue of our products. We cannot predict the likelihood, nature or extent of adverse governmental regulation that might arise from future legislative or administrative action, either in the U. S. or abroad. Orphan Drug ActUnder the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200, 000 individuals in the United States, or more than 200, 000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making available in the United States a drug for this type of disease or condition will be recovered from sales in the United States for that drug. Orphan ~~drug~~ **Drug** designation must be requested before submitting an NDA or BLA. After the FDA grants orphan drug designation, the name of the sponsor, identity of the drug or biologic and its potential orphan use are disclosed publicly by the FDA. The orphan drug designation does not shorten the duration of the regulatory review or approval process, but does provide certain advantages, such as a waiver of Prescription Drug User Fee Act (" PDUFA ") fees, enhanced access to FDA staff and potential waiver of pediatric research requirements. If a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications, including a full NDA, to market the same drug or biologic for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity. Orphan drug exclusivity does not prevent FDA from approving a different drug or biologic for the same disease or condition, or the same drug or biologic for a different disease or condition. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the application user fee. A designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. In addition, exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition. ~~Orphan~~ **26Accelerated ApprovalThere are a variety of pathways under which applicants may seek expedited approval from FDA, including Fast Track, breakthrough therapy, priority review and accelerated approval. Fast Track is a process designed to facilitate the development and expedite the review of investigational drugs to treat serious conditions and fill an unmet medical need. Drugs that receive Fast Track designation may be eligible for more frequent communications and meetings with the FDA to discuss the drug' s development plan, including the design of the proposed clinical trials, use of biomarkers and the extent of data needed to support approval. Drugs with Fast Track designation may also qualify for accelerated approval and priority review of new drug applications if relevant criteria are met. However, Fast Track designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process. The FDA accelerated approval program provides for early approval of drugs based on a drug on a clinical trial (s) showing that the drug meets a surrogate or an intermediate clinical endpoint rather than a clinical benefit endpoint. Accelerated approval is possible for drugs for serious conditions that fill an unmet medical need. Under priority review, the FDA reviews an application in six months rather than ten months after it is accepted for filing. A surrogate endpoint used for accelerated approval is a marker, such as a laboratory measurement, that is thought to predict clinical benefit, but is not itself a measure of clinical benefit.**

Likewise, an intermediate clinical endpoint is a measure of a therapeutic effect that is considered reasonably likely to predict the clinical benefit of a drug, such as an effect on irreversible morbidity and mortality. Because it sometimes can take many years for a drug trial to show a clinical benefit, the use of a surrogate endpoint or an intermediate clinical endpoint can significantly shorten the time required to complete clinical trials and obtain FDA approval. If a drug receives an accelerated approval, the company that sponsored the application must conduct a post- approval trial to confirm the anticipated clinical benefit. These trials are known as Phase 4 or post- approval confirmatory trials. If the confirmatory trial shows that the drug actually provides a clinical benefit, then the FDA grants traditional approval for the drug. Failure to conduct required post- approval studies, or confirm a clinical benefit during post- marketing studies, will allow the FDA to withdraw the drug from the market on an expedited basis. All promotional materials for drug candidates approved under accelerated regulations are subject to prior review by the FDA. If the confirmatory trial does not show that the drug provides clinical benefit, FDA has regulatory procedures in place that could lead to removing the drug from the market. Rare Pediatric Disease VouchersThe Rare Pediatric Disease Voucher Program is intended to encourage development of new drug and biological products for prevention and treatment of certain rare pediatric diseases. Although there are existing incentive programs to encourage the development and study of drugs and biologics for rare diseases, pediatric populations, and unmet medical needs, this program provides an additional incentive for the development of drugs and biologics for rare pediatric diseases, which may be used alone or in combination with other incentive programs. A rare pediatric disease is defined as a disease that is a serious or life- threatening disease in which the serious or life- threatening manifestations primarily affect individuals aged from birth to 18 years, including age groups often called neonates, infants, children, and adolescents; and is a rare disease or condition as defined in the FDCA, which includes diseases and conditions that affect fewer than 200, 000 persons in the United States and diseases and conditions that affect a larger number of persons and for which there is no reasonable expectation that the costs of developing and making available the product in the United States can be recovered from sales of the product in the United States. The sponsor of an application for a drug product that obtains rare pediatric disease designation may be eligible for a voucher that can be used or sold to obtain a priority review for a subsequent application submitted under section 505 (b) (1) of the FDCA or section 351 of the PHS Act. A rare pediatric disease drug product must meet certain eligibility requirements for a priority voucher at the time the sponsor seeks approval. The rare pediatric disease priority review voucher program was most recently re- authorized by Congress through December 20, 2024, with the potential for priority review vouchers to be granted through September 30, 2026. If a BLA for VCN- 01 for the treatment of retinoblastoma is approved by the FDA by September 30, 2026, we may be eligible to receive a priority review voucher. 27Pediatric Information and Pediatric ExclusivityUnder the Pediatric Research Equity Act (“ PREA ”), certain NDAs and BLAs and certain supplements to an NDA or BLA must contain data to assess the safety and efficacy of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may grant deferrals for submission of pediatric data or full or partial waivers. The Food and Drug Administration Safety and Innovation Act (“ FDASIA ”), amended the FDCA to require that a sponsor who is planning to submit a marketing application for a drug that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration submit an initial Pediatric Study Plan (“ PSP ”) within 60 days of an end- of- Phase 2 meeting or, if there is no such meeting, as early as practicable before the initiation of the Phase 3 or Phase 2 / 3 study. The initial PSP must include an outline of the pediatric study or studies that the sponsor plans to conduct, including study objectives and design, age groups, relevant endpoints and statistical approach, or a justification for not including such detailed information, and any request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric studies along with supporting information. The FDA and the sponsor must reach an agreement on the PSP. A sponsor can submit amendments to an agreed- upon initial PSP at any time if changes to the pediatric plan need to be considered based on data collected from preclinical studies, early phase clinical trials and / or other clinical development programs. The Best Pharmaceuticals for Children Act, or BPCA, provides NDA holders a six- month extension of any exclusivity — patent or non- patent — for a drug if certain conditions are met. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods and patent terms. Conditions for exclusivity include the FDA’ s determination that information relating to the use of a new drug in the pediatric population may produce health benefits in that population, the FDA’ s written request for pediatric studies, and the applicant’ s agreeing to perform, and reporting on, the requested studies within the statutory timeframe. Applications under the BPCA are treated as priority applications, with all of the benefits that designation confers. Drug Development in the European UnionOrphan Drug Designation is also available in Europe from the European Medicines Agency (EMA) and provides for 10 years of market exclusivity if granted. The requirements, costs and timing for obtaining and maintaining EMA Orphan Drug Designation differ from the FDA. In May 2011, the Committee for Orphan Medicinal Products (" COMP") from the EMA recommended granting Orphan Medicinal Product Designation to VCN- 01 for the treatment of pancreatic cancer and in June 2011, the European Commission confirmed the designation under Regulation (" EC") No 141 / 2000 of the European Parliament and of the Council. In ~~February~~ **October** ~~2022~~ **2024** , the ~~FDA~~ **European Commission adopted the European Medicines Agency (EMA) recommendation to** ~~granted~~ -- **grant** Orphan ~~Drug~~ **Medicinal Product** ~~designation~~ **Designation** to VCN- 01 for the treatment of retinoblastoma. **The European Commission confirmed the designation under Regulation (" EC") No 141 / 2000 of the European Parliament and of the Council.** In ~~June 2023~~ **the European Union** , **our future products may also be subject to extensive regulatory requirements. Similar to the United States, the marketing of medicinal products is subject to the granting of marketing authorizations by regulatory agencies. Also, as in the United States, the various phases of pre- clinical and clinical research in the European Union are subject to significant regulatory controls. In the European Union, approval of new**

medicinal products can be obtained through one of three processes: the mutual recognition procedure, the centralized procedure and the decentralized procedure. We intend to determine which process we will follow, if any, in the future. 28Mutual Recognition Procedure: An applicant submits an application in one European Union member state, known as the reference member state. Once the reference member state has granted the marketing authorization, the applicant may choose to submit applications in other concerned member states, requesting them to mutually recognize the marketing authorizations already granted. Under this mutual recognition process, authorities in other concerned member states have 55 days to raise objections, which must then be resolved by discussion among the concerned member states, the reference member state and the applicant within 90 days of the commencement of the mutual recognition procedure. If any disagreement remains, all considerations by authorities in the concerned member states are suspended and the disagreement is resolved through an arbitration process. The mutual recognition procedure results in separate national marketing authorizations in the reference member state. Centralized Procedure: This procedure is currently mandatory for products developed by means of a biotechnological process and optional for new active substances and other " innovative medicinal products with novel characteristics. " Under this procedure, an application is submitted to the European Agency for the Evaluation of Medical Products. Two European Union member states are appointed to conduct an initial evaluation of each application. These countries each prepare an assessment report that is then used as the basis of a scientific opinion of the Committee on Proprietary Medical Products. If this opinion is favorable, it is sent to the European Commission, which drafts a decision. After consulting with the member states, the European Commission adopts a decision and grants a marketing authorization, which is valid throughout the European Union and confers the same rights and obligations in each of the member states as a marketing authorization granted by that member state. Decentralized Procedure: The most recently introduced of the three processes for obtaining approval of new medicinal processes in the European Union, the decentralized procedure is similar to the mutual recognition procedure described above, but with differences in the timing that key documents are provided to concerned member states by the reference member state, the overall timing of the procedure and the possibility of, among other things, " clock stops " during the procedure. Post- Marketing RequirementsFollowing approval of a new product, a pharmaceutical company and the approved product are subject to continuing regulation by the FDA ~~granted Orphan~~ **and other regulatory authorities, including, among other things, monitoring and recordkeeping activities, reporting to applicable regulatory authorities of adverse experiences with the product, providing the regulatory authorities with updated safety and efficacy information, product sampling and distribution requirements, and complying with promotion and advertising requirements, which include, among others, standards for direct- to- consumer advertising, restrictions on promoting drugs for uses or in patient populations not described in the drug' s approved labeling (known as " off- label use "), and limitations on industry- sponsored scientific and educational activities. Although physicians may prescribe legally available drugs for off- label uses, drugs may be marketed only for the approved indications and in accordance with the provisions of the approved labeling. Modifications or enhancements to the products or labeling or changes of site of manufacture are often subject to the approval of the FDA and other regulators, which may or may not be received or may result in a lengthy review process. The FDA regulations require the products be manufactured in specific approved facilities and in accordance with current good manufacturing practices, and NDA holders must list their products and register their manufacturing establishments with the FDA. These regulations also impose certain organizational, procedural and documentation requirements with respect to manufacturing and quality assurance activities.** Drug ~~Designation~~ **manufacturers and other entities involved in the manufacture and distribution of approved drugs are subject** to ~~VCN- 01~~ **periodic unannounced inspections by the FDA and certain state agencies** for **compliance with current good manufacturing practice and other laws. NDA holders using contract manufacturers, laboratories or packagers are responsible for the selection and monitoring of qualified firms. These firms are subject to inspections by the FDA at any time, and the discovery of violative conditions could result in enforcement actions that interrupt the operation of any such facilities or the ability to distribute products manufactured, processed or tested by** ~~the~~ **them** ~~treatment of pancreatic cancer~~ . ~~26Other~~ **29Other** Healthcare Laws and Compliance RequirementsIn the United States, the research, manufacturing, distribution, sale and promotion of drug products and medical devices are potentially subject to regulation by various federal, state and local authorities in addition to the FDA, including the U. S. Department of Justice, state Attorneys General, and other state and local government agencies. The federal Anti- Kickback Statute prohibits any person, including a prescription drug manufacturer (or a party acting on its behalf), from knowingly and willfully soliciting, receiving, offering or providing remuneration, directly or indirectly, to induce or reward either the referral of an individual, or the furnishing, recommending or arranging for a good or service, for which payment may be made under a federal healthcare program such as the Medicare and Medicaid programs. The federal False Claims Act **(" FCA ")** imposes liability on any person or entity that, among other things, knowingly presents or causes to be presented, a false or fraudulent claim for payment by a federal healthcare program. The qui tam provisions of the **FCA** ~~False Claims Act~~ allow a private individual to bring civil actions on behalf of the federal government alleging that the defendant has submitted a false claim to the federal government, and to share in any monetary recovery. In addition, various states have enacted anti- kickback statues and false claims laws analogous to the ~~False Claims~~ **FCA The Federal Physician Payments Sunshine** Act ~~.~~ **within the Affordable Care Act, or the ACA, and its implementing regulations, require that certain manufacturers of drugs, devices, biological and medical supplies for which payment is available under Medicare, Medicaid or the Children' s Health Insurance Program (with certain exceptions) to report on an annual basis information related to certain payments or other transfers of value made or distributed to physicians and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, the physicians and teaching hospitals and certain ownership and investment interests held by physicians and their immediate family members, with the information made publicly available on a searchable website** Also, the Health

Insurance Portability and Accountability Act of 1996 (HIPAA) **)** ~~created several federal crimes~~ , **as amended by** ~~including healthcare fraud, and false statements relating to~~ the **Health Information Technology** ~~delivery of or payments~~ for ~~healthcare benefits, items or services. HIPAA~~ **Economic and Clinical Health Act (HITECH)** and its implementing regulations ~~also established uniform federal~~ **, imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA' s privacy and security** standards ~~for certain~~ **directly applicable to** " **business associates " — independent contractors or agents of** covered entities **that receive or obtain** ~~" (healthcare providers, health plans and healthcare clearinghouses) governing the conduct of certain electronic healthcare transactions and protecting the security and privacy of~~ protected health information **in connection with providing a service on behalf of a covered entity. HITECH also created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions** . Because of the breadth of these and other laws and the narrowness of available statutory and regulatory exemptions, it is possible that some of our business activities could be subject to challenge under one or more of such laws. If our operations are found to be in violation of any of the federal and state laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including criminal and significant civil monetary penalties, damages, fines, imprisonment, exclusion from participation in government healthcare programs, injunctions, recall or seizure of products, total or partial suspension of production, denial or withdrawal of pre- marketing product approvals, private " qui tam " actions brought by individual whistleblowers in the name of the government or refusal to allow us to enter into supply contracts, including government contracts, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. In order to market any product outside of the United States, a company also must comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of products. Whether or not it obtains FDA approval for a product, an applicant will need to obtain the necessary approvals by the comparable foreign regulatory authorities before it can initiate clinical trials or market products in those countries or jurisdictions. Specifically, the process governing approval of medicinal products in the EU generally follows the same lines as in the United States. It entails satisfactory completion of pharmaceutical development, nonclinical studies and adequate and well-controlled clinical trials to establish the safety and efficacy of the medicinal product for each proposed indication. It also requires the submission to relevant competent authorities for clinical trials authorization and to the EMA or to competent authorities in EU Member States for a marketing authorization application, or MAA, and granting of a marketing authorization by competent authorities in EU Member States or the European Commission before the product can be marketed and sold in the EU. ~~27Data~~ **30Data** PrivacyStrict data privacy laws regulating the collection, transmission, storage and use of employee data and consumers' personally- identifying information are evolving in the European Union, U. S. and other jurisdictions in which we operate. Outside of the United States, the laws, regulations and standards in many jurisdictions apply broadly to the collection, use, and other processing of personal information. For example, in the European Union, the collection and use of personal data are governed by the provisions of the General Data Protection Regulation (the " GDPR "). The GDPR, together with national legislation, regulations and guidelines of the European Union. member states governing the processing of personal data, impose strict obligations on entities subject to the GDPR, including but not limited to: (i) accountability and transparency requirements, and enhanced requirements for obtaining valid consent from data subjects; (ii) obligations to consider data protection as any new products or services are developed and to limit the amount of personal data processed; (iii) obligations to comply with the data protection rights of data subjects; and (iv) obligations to report certain personal data breaches to governmental authorities and individuals. Data protection authorities from the different E. U. member states and other European countries may enforce the GDPR and national data protection laws differently, and introduce additional national regulations and guidelines, which adds to the complexity of processing European personal data. Failure to comply with the requirements of the GDPR and the related national data protection laws may result in significant monetary fines and other administrative penalties (the GDPR authorizes fines for certain violations of up to 4 % of global annual revenue or € 20 million, whichever is greater) as well as civil liability claims from individuals whose personal data was processed. Additionally, expenses associated with compliance could reduce our operating margins. The GDPR also prohibits the transfer of personal data from the E. U. to countries outside of the E. U. unless made to a country deemed by the European Commission to provide adequate protection for personal data or accomplished by means of an approved data transfer mechanism (e. g., standard contractual clauses). Data protection authority guidance and enforcement actions that restrict companies' ability to transfer data may increase risk relating to data transfers or make it more difficult or impossible to transfer E. U. personal data to the U. S. **Environmental, Health, and Safety RegulationWe are subject to numerous federal, state and local environmental, health and safety (" EHS "), laws and regulations relating to, among other matters, safe working conditions, product stewardship, environmental protection, and handling or disposition of products, including those governing the generation, storage, handling, use, transportation, release, and disposal of hazardous or potentially hazardous materials, medical waste, and infectious materials that may be handled by our research laboratories. Some of these laws and regulations also require us to obtain licenses or permits to conduct our operations. If we fail to comply with such laws or obtain and comply with the applicable permits, we could face substantial fines or possible revocation of our permits or limitations on our ability to conduct our operations. Certain of our development activities involve use of hazardous materials, and we believe we are in compliance with the applicable environmental laws, regulations, permits, and licenses. However, we cannot ensure EHS liabilities will not develop in the future. EHS laws and regulations are complex, change frequently and have tended to become more stringent over time. Although the costs to comply with applicable laws and regulations, have not been**

material, we cannot predict the impact on our business of new or amended laws or regulations or any changes in the way existing and future laws and regulations are interpreted or enforced, nor can we ensure we will be able to obtain or maintain any required licenses or permits. Competitive EnvironmentThe pharmaceutical and biotechnology industries are characterized by rapidly evolving technology and intense competition. Our competitors include major multi- national pharmaceutical companies and biotechnology companies developing both generic and proprietary therapies to treat serious diseases. Many of these companies are well- established and possess technical, human, research and development, financial, and sales and marketing resources significantly greater than ours. In addition, many of our potential competitors have formed strategic collaborations, partnerships and other types of joint ventures with larger, well established industry competitors that afford these companies potential research and development and commercialization advantages in the therapeutic areas we are currently pursuing. Academic research centers, governmental agencies and other public and private research organizations are also conducting and financing research activities which may produce products directly competitive to those being developed by us. In addition, many of these competitors may be able to obtain patent protection, obtain FDA and other regulatory approvals and begin commercial sales of their products before us. ~~Our~~ **31Our** oncology product candidates compete with all other oncology products being developed for the indications that we are focusing oncolytic virus (OV) products being developed by third parties. Only three ~~oncolytic virus (~~OV ~~)~~ products have been approved in different global markets. Amgen Inc.' s Imlygic ® (T- VEC, OncoVEX) for melanoma (USA); Daiichi Sankyo Company, Limited ' s DELYTACT ® for malignant glioma (Japan) and Shanghai Sunway Biotech Co., Ltd Oncorine ® for patients with late- stage refractory nasopharyngeal cancer (China) **. A BLA filed by Replimune, Inc. for their OV RP1 (vusolimogene oderparepvec) in combination with nivolumab for patients with advanced melanoma has been accepted by the FDA with a Prescription Drug User Fee Act (PDUFA) action date of July 22, 2025. In June 2024, CG Oncology, Inc. announced that their Phase 3 OV cretostimogene grenadenorepvec was available in the U. S. for patients with BCG- unresponsive non- muscle invasive bladder cancer (" NMIBC ") who meet certain program eligibility criteria** . More than 60 companies have publicly identified that they are pursuing clinical development of different forms of OV products. Adenoviruses are the most commonly used viruses in these programs, with modified adenoviruses under development by companies including AdCure Bio LLC, Calidi Biotherapeutics, Inc., Candel Therapeutics, Inc., CG Oncology, Inc., Elicera Therapeutics AB, EpicentRx, Inc., GeneMedicine, Co Ltd., IconOVir Bio, Inc., Lokon Pharma AB, Memgen, Inc., Multivir, Inc., NewGenPharm Incorporation, Oncolys BioPharma, Inc., Orca Therapeutics B. V., Akamis Bio Ltd (formerly PsiOxus Therapeutics Ltd), Shanghai Sunway Biotech Co., Ltd, Circio Holding ASA (formerly Targovax Oy | Targovax ASA), ~~Tcolytics~~ **Theolytics** Ltd, Tessa Therapeutics, TILT Biotherapeutics, Ltd., and Valo Therapeutics Oy. ~~28OV~~ **OV** products have been or are being developed using other virus backbones, including: arenavirus (Hookipa Pharma, Inc.), Coxsackie virus (Viralytics Ltd., Oncorus Inc.); herpes simplex virus (Amgen, Inc., Candel Therapeutics, Inc., Daiichi Sankyo Company Ltd., ImmVira Co. Ltd, Replimune, Inc., Takara Bio, Inc., Treovir LLC, Virogin Biotech, Inc. Wuhan Binhui Biotechnology Co., Ltd.); Maraba virus (Turnstone Biologics, Inc.); measles virus (Themis Biosciences GmbH, Vyriad, Inc.); myxoma virus (OncoMyx Therapeutics, Inc.); parvovirus (Oryx GmbH & Co. KG), reovirus (Oncolytics Biotech, Inc.); poliovirus (Istari Oncology, Inc.); Seneca Valley virus (Seneca Therapeutics Inc., Oncorus Inc.); vesicular stomatitis virus (Boehringer Ingelheim, Cytonus Therapeutics, Inc., Vyriad, Inc.); and vaccinia viruses (Genelux Corporation, Imugene Ltd, Joint Biosciences Ltd, KaliVir Immunotherapeutics LLC, SillaJen, Inc., Transgene SA, Turnstone Biologics, Corp.). OV companies that have identified pancreatic cancer or PDAC as a proposed clinical indication include Akamis Bio Ltd, Boehringer Ingelheim GmbH, Candel Therapeutics, Inc., GeneMedicine, Co Ltd., Lokon Pharma AB, Memgen, Inc., NewGenPharm Incorporation, Oncolytics Biotech, Oryx GmbH & Co. KG, Takara Bio, Inc., TILT Biotherapeutics Ltd), V2ACT Therapeutics ™ LLC (a Genelux Corporation joint venture), Virogin Biotech, Inc., and Wuhan Binhui Biotechnology Co., Ltd. OV companies that have identified retinoblastoma as a potential target indication include Seneca Therapeutics Inc. and Shanghai Sunway Biotech Co., Ltd. Theriva Biologics' OV products are designed to be systemically, intratumorally or intravitreally injected; selectively replicate only in tumor cells versus normal host cells; have reduced liver tropism compared to wild type adenovirus type 5; and express an enzyme (PH20 hyaluronidase) that degrades the tumor stroma barrier. If confirmed in Phase 2 and later clinical trials, we believe these features significantly differentiate Theriva Biologics' products from competing OVs and will enable our products to be co- administered with other therapeutic modalities such as chemotherapy and immuno- oncology products to improve cancer treatment outcomes. Companies that currently sell or are developing proprietary products for the prevention and treatment of C. difficile infection include: Actelion Pharmaceutical Ltd., Artugen Therapeutics, Inc., AzurRx, Inc., Deinove, Pfizer Inc., Merck & Co. Inc., Merus B. V., Pfizer Inc., Rebiotix, Inc., Seres Therapeutics, Inc., Summit Therapeutics plc. and Vedanta Biosciences Inc. Companies that sell or are developing products for the treatment or prevention of acute graft- versus- host- disease (aGVHD) include: Amgen, Inc., Astellas Pharma, Janssen Biotech, Inc., Mallinckrodt plc, Mesoblast, Inc., Novartis International AG, Pfizer, Inc. Roche AG and Takeda Pharmaceutical Company Ltd. Not only do our product candidates compete with other product candidates being developed for similar or the same indications, we also compete for employees **,** ~~and for~~ clinical trial sites **, and clinical trial participants** . ~~Corporate~~ **32Corporate** HistoryOur predecessor, Sheffield Pharmaceuticals, Inc., was incorporated in 1986, and in 2006 engaged in a reverse merger with Pipex Therapeutics, Inc., a publicly- traded Delaware corporation formed in 2001. After the reverse merger, we changed our name to Pipex Pharmaceuticals, Inc., and in October 2008 we changed our name to Adeona Pharmaceuticals, Inc. On October 15, 2009, we engaged in a merger with a wholly owned subsidiary for the purpose of reincorporating in the State of Nevada. On February 15, 2012, we changed our name to Synthetic Biologics, Inc. On August 10, 2018, we effected a one for thirty- five reverse stock split of our authorized, issued and outstanding common stock. On July 15, 2022, we effected a one for ten reverse stock split of our authorized, issued and outstanding common stock. On October 12, 2022, we changed our name to Theriva Biologics, Inc. **On August 26, 2024, we effected a one for twenty- five reverse stock split of our authorized, issued and outstanding common stock.** ~~29Human~~ -- **Human** CapitalWe believe that our success depends upon

our ability to attract, develop and retain key personnel. As of March ~~25~~ **6**, ~~2024~~ **2025**, we employed 22 individuals, all but ~~one~~ **two** of whom are full- time employees ~~, of which~~ **. Six (** 6 **)** were part of our research and clinical development team in the United States and ~~9 are~~ **Ten (10) were** part of VCN' s research and clinical development team located in Spain, **Two (** 2 **)** are part of VCN' s management team located in Spain and **Four (** 4 **) (including the CEO)** are part of our financial reporting and accounting team located in the United States. A significant number of our management and professional employees have had prior experience with pharmaceutical, biotechnology or medical product companies. None of our employees in the United States are covered by collective bargaining agreements, and management considers relations with our employees to be in good standing. As is the usual situation in Spain, all the employees are currently covered by a collective bargaining system specific for the pharma sector. Although we continually seek to add additional talent to our work force, management believes that it has sufficient human capital to operate its business successfully. Competitive Pay and BenefitsOur compensation programs are designed to align the compensation of our employees with our performance and to provide the proper incentives to attract, retain and motivate employees to achieve superior results. The structure of our compensation programs balances incentive earnings for both short- term and long- term performance. Specifically: ● we provide employee wages that are competitive and consistent with employee positions, skill levels, experience, knowledge and geographic location; ● we engage nationally recognized outside compensation and benefits consulting firms to independently evaluate the effectiveness of our executive compensation and benefit programs and to provide benchmarking against our peers within the industry; ● we align our executives' long- term equity compensation with our shareholders' interests by linking realizable pay with stock performance; and ● all employees are eligible for health insurance, paid and unpaid leaves, a retirement plan and life and disability / accident coverage. We also offer a variety of voluntary benefits that allow employees to select the options that meet their needs, including flexible time- off, telemedicine, and unpaid parental leave. ~~Health and SafetyThe health and safety of our employees is our highest priority, and this is consistent with our operating philosophy. Accordingly, with the global spread of the ongoing novel coronavirus pandemic, we have implemented plans designed to address and mitigate the impact of the COVID- 19 pandemic on the safety of our employees and our business, which include: ● adding work from home flexibility; ● adjusting attendance policies to encourage those who are sick to stay home; ● increasing cleaning protocols across all locations; and~~ ● initiating regular communication regarding impacts of the COVID- 19 pandemic, including health and safety protocols and procedures. ~~30Available~~ **33Available** InformationAdditional information about Theriva Biologics is contained at our website, www. therivabio. com. Information contained on our website is not incorporated by reference into, and does not form any part of, this Annual Report. We have included our website address as a factual reference and do not intend it to be an active link to our website. Our Annual Reports on Form 10- K, Quarterly Reports on Form 10- Q and Current Reports on Form 8- K and amendments to those reports filed or furnished pursuant to Section 13 (a) or 15 (d) of the Exchange Act are available free of charge through the investor relations page of our internet website as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Securities and Exchange Commission (the " SEC "). The following Corporate Governance documents are also posted on our website: Code of Conduct, Code of Ethics for Financial Management and the Charters for the Audit Committee, Compensation Committee and Nominations Committee of the Board of Directors. Our phone number is (301) 417- 4364 and our facsimile number is (301) 417- 4367. The SEC maintains an internet site that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the Commission. The address of that website is www. sec. gov. ~~Item~~ **34Item** 1A. Risk Factors. Investing in our securities involves a high degree of risk. In addition to the risks related to our business set forth in this Annual Report and the other information included in this Annual Report, you should carefully consider the risks described below before purchasing our securities. Additional risks, uncertainties and other factors not presently known to us or that we currently deem immaterial may also impair our business operations. RISKS RELATED TO OUR FINANCIAL POSITION AND CAPITAL REQUIREMENTSOur auditor' s report on our consolidated financial statements contains an explanatory paragraph regarding our ability to continue as a going concern. Our consolidated financial statements as of December 31, ~~2023~~ **2024** have been prepared under the assumption that we will continue as a going concern for the next twelve months. In addition, our independent registered public accounting firm has issued a report that includes an explanatory paragraph referring to our recurring losses from operations (anticipated continued losses in the future) and net capital deficiency that raise substantial doubt in our ability to continue as a going concern without additional capital becoming available. Our ability to continue as a going concern is dependent upon our ability to obtain additional equity or debt financing, attain further operating efficiencies, reduce expenditures, and, ultimately, to generate revenue. Our consolidated financial statements as of December 31, ~~2023~~ **2024** did not include any adjustments that might result from the outcome of this uncertainty. We expect that our current cash will be able to fund operations ~~through the fourth quarter of 2024 and~~ into the ~~first~~ **third** quarter of 2025 but will not be sufficient to fund operations for twelve months from the date of the filing of this Annual Report. ~~We~~ **35We** will need to raise additional capital to operate our business and our failure to obtain funding when needed may force us to delay, reduce or eliminate certain of our development programs or commercialization efforts. During the year ended December 31, ~~2023~~ **2024**, our operating activities used net cash of approximately $ ~~19~~ **16**. ~~0~~ **9** million and as of December 31, ~~2023~~ **2024** our cash and cash equivalents were $ ~~23~~ **11**. ~~2~~ **6** million. With the exception of the three months ended December 31, 2017 and June 30, 2010, we have experienced significant losses since inception and have a significant accumulated deficit. As of December 31, ~~2023~~ **2024**, our accumulated deficit totaled approximately $ ~~309~~ **335**. ~~3~~ **0** million on a consolidated basis. Pursuant to the VCN Purchase Agreement, we have agreed to use reasonable efforts to commercialize VCN- 01 and we agreed as a post- closing covenant to commit to fund VCN' s research and development programs, including but not limited to VCN- 01 PDAC Phase 2 clinical trial, VCN- 01 RB pivotal trial and necessary G & A within a budgetary plan of approximately $ 27. 8 million ~~over the next three years~~. We expect to incur additional operating losses in the future and therefore expect our cumulative losses to increase **. With the exception of the quarter ended June 30, 2010, and limited laboratory revenues from Adeona Clinical Laboratory, which we sold in March 2012, we have**

generated very minimal revenues . We do not expect to derive revenue from any source in the near future until we or our potential partners successfully commercialize our products. We expect our expenses to increase in connection with our anticipated activities, particularly as we continue research and development, initiate and conduct clinical trials, and seek marketing approval for our product candidates. Until such time as we receive approval from the FDA and other regulatory authorities for our product candidates, we will not be permitted to sell our products and therefore will not have product revenues from the sale of products. For the foreseeable future we will have to fund all of our operations and capital expenditures from equity and debt offerings, cash on hand, licensing and collaboration fees and grants, if any ~~. 31We expect that our current cash will be able to fund operations through the fourth quarter of 2024 and into the first quarter of 2025 but will not be sufficient to fund operations for twelve months from the date of the filing of this Annual Report~~ . We will need to raise additional capital to fund our operations and meet our current timelines and we cannot be certain that funding will be available on acceptable terms on a timely basis, or at all. **The amount of government funding available for grants is dependent upon governmental budgets over which we have no control and which change with new administrations.** Based on our current plans, **we expect that** our **current** cash ~~and cash equivalents~~ will **be able to fund operations into the third quarter of 2025 but will not be sufficient to fund our operations for the next twelve months and will only** be sufficient to complete our planned clinical trials of VCN- 01 (in PDAC and retinoblastoma), **but may not be sufficient for additional trials of VCN- 01, SYN- 020 or SYN- 004, or to complete the last cohort of the** Phase 1a / 2a clinical trial of ~~SYN- 004, but will not be sufficient for additional trials of VCN- 01, SYN- 020 or~~ SYN- 004, which are expected to require significant cash expenditures. In addition, based on the significant anticipated cost of a Phase 3 clinical program in a broad indication for SYN- 004, we expect it will not be feasible for us to initiate and complete this trial at this time without a partner given the capital constraints tied to our current market cap and share price. **We intend to** ~~As part of our strategic transformation into an oncology focused~~ -- **focus** ~~company, we are exploring value creation options~~ **our capital on our VCN- 01 clinical trials and do not intend to provide further funding** for our **development of** SYN- 004 ~~and~~ **internally but intend to out- license or partner further development of** SYN- **004** ~~020 assets, including out- licensing or partnering~~ . Further development of VCN' s product candidates will require additional funding. To the extent that we raise additional funds by issuing equity securities, our stockholders may experience significant dilution. Any debt financing, if available, may involve restrictive covenants that may impact our ability to conduct our business and also have a dilutive effect on our stockholders. A failure otherwise to secure additional funds when needed in the future whether through an equity or debt financing or a sufficient amount of capital without a strategic partnership could result in us being unable to complete planned preclinical and clinical trials or obtain approval of our product candidates from the FDA and other regulatory authorities. In addition, we could be forced to delay, discontinue or curtail product development, forego sales and marketing efforts, and forego licensing in attractive business opportunities. Our ability to raise capital through the sale of securities may be limited by the rules of the SEC and NYSE American **LLC (" NYSE American ")** that place limits on the number and dollar amount of securities that may be sold. There can be no assurances that we will be able to raise the funds needed, especially in light of the fact that our ability to sell securities registered on our registration statement on Form S- 3 will be limited until such time the market value of our voting securities held by non- affiliates is $ 75 million or more. We also may be required to seek collaborators for our product candidates at an earlier stage than otherwise would be desirable and on terms that are less favorable than might otherwise be available. We expect to continue to incur significant operating and capital expenditures and we will need additional funds to support our operations, and such funding may not be available to us on acceptable terms, or at all, which would force us to delay, reduce or suspend our research and development programs and other operations or commercialization efforts. We have a history of losses and we have incurred, and will continue to incur, substantial losses and negative operating cash flow. Even if we succeed in developing and commercializing one or more of our product candidates, we may still incur substantial losses for the foreseeable future and may not sustain profitability. We anticipate a need for additional employees as we undertake later stage clinical trials. We have also incurred certain obligations pursuant to the terms of the VCN Purchase Agreement including the assumption of $ 2. 4 million of liabilities and have agreed to a post- closing covenant to commit to fund research and development of VCN- 01 and OV pipeline programs, including but not limited to the VCN- 01 PDAC Phase 2 trial, a VCN- 01 RB pivotal trial and necessary G & A within a budgetary plan of approximately $ 27. 8 million **with $ 5** . **0 million remaining as of December 31, 2024.** ~~Further~~ **36Further** development of VCN- 01 and pipeline OV product candidates will require additional expenditures. We also expect to continue to incur significant operating and capital expenditures and anticipate that our expenses will substantially increase in the foreseeable future as we do the following: ● continue to undertake preclinical development of our OV pipeline and mid and late- stage clinical trials for our product candidates, including VCN- 01; ● seek regulatory approvals for our product candidates; ● develop our product candidates for commercialization; ● implement additional internal systems and infrastructure; ● license or acquire additional technologies; ● lease additional or alternative office facilities; ● manufacture product for clinical trials and commercial use; and ● hire additional personnel, including members of our management team. ~~32We~~ **We** may experience negative cash flow for the foreseeable future as we fund our development and clinical programs with capital expenditures. As a result, we will need to raise additional capital or generate significant revenues in order to achieve and maintain profitability. We may not be able to generate these revenues or achieve profitability in the future. Our failure to achieve or maintain profitability, which we do not anticipate will occur in the near future, could negatively impact the value of our common stock and underlying securities. There can be no assurance that funding will be available on acceptable terms on a timely basis, or at all. The various ways that we could raise capital carry potential risks. Any additional sources of financing will likely involve the issuance of our equity securities, which will have a dilutive effect on our stockholders. If we raise funds through collaborations and licensing arrangements, we might be required to relinquish significant rights to our technologies or tests or grant licenses on terms that are not favorable to us. The **amount of government funding available for grants is dependent upon governmental budgets over which we have no control and which change with new administrations. The** actual amount of funds we will need to operate is subject to many

risk factors, some of which are beyond our control. The actual amount of funds we will need to operate is subject to many factors, some of which are beyond our control. These factors include the following: ● the progress of our research activities and ability to attract patients; ● the number and scope of our research programs; ● the progress of our preclinical and clinical development activities; ● the progress of the development efforts of parties with whom we have entered into research and development agreements and amount of funding received from partners and collaborators; ● our ability to maintain current research and development licensing arrangements and to establish new research and development and licensing arrangements; ● our ability to achieve our milestones under licensing arrangements; ● the costs associated with manufacturing- related services to produce materials for use in our clinical trials; ● the costs involved in prosecuting and enforcing patent claims and other intellectual property rights; **37** ● the costs incurred to screen and enroll patients; and ● ~~The~~ **the** costs and timing of regulatory approvals. We have based our estimate on assumptions that may prove to be wrong. We may need to obtain additional funds sooner or in greater amounts than we currently anticipate. Potential sources of financing include strategic relationships, public or private sales of our shares or debt and other sources. Additionally, we may seek to access the public or private equity markets when conditions are favorable due to our long- term capital requirements. We do not have any committed sources of financing at this time, and it is uncertain whether additional funding will be available when we need it on terms that will be acceptable to us, or at all. We currently have a limited operating history as an oncology company, no products approved for commercial sale, have no significant source of revenue and may never generate significant revenue. We are a clinical- stage biopharmaceutical company that began to focus on development of oncolytic viruses for treatment of various types of cancer in 2022. We have never generated any product revenue, do not expect to generate revenue in the near future and do not have any products approved for sale. Our operations to date have been primarily focused on developing our product candidates. We have not yet successfully obtained marketing approval, manufactured any product candidate at commercial scale, or conducted sales and marketing activities that will be necessary to successfully commercialize our product candidates. Consequently, predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing product candidates. ~~33All~~ -- **All** of our existing product candidates are in various stages of development and will require extensive additional clinical evaluation, regulatory review and approval, significant marketing efforts and substantial investment before they could provide us with any revenue. As a result, even if we successfully develop, achieve regulatory approval and commercialize our products, we may be unable to generate revenue for many years, if at all. We do not anticipate that we will generate revenue from product sales for at least several years, if at all. If we are unable to generate revenue from product sales, we will not become profitable, and we may be unable to continue our operations. Our ability to generate revenue depends heavily on: ● our ability to raise additional capital on a timely basis to continue to fund our clinical trials; ● demonstration in current and future clinical trials that our lead product candidate, VCN- 01, as well as each of our other product candidates, is safe and effective; and ● our ability to seek and obtain regulatory approvals, including with respect to the indications we are seeking; Even if we receive regulatory approval for the sale of any of our product candidates, we do not know when we will begin to generate revenue, if at all. Our ability to generate revenue depends on a number of factors, including our ability to: ● set an acceptable price for our products and obtain coverage and adequate reimbursement from third- party payors; ● establish sales, marketing, manufacturing and distribution systems; ● add operational, financial and management information systems and personnel, including personnel to support our clinical, manufacturing and planned future clinical development and commercialization efforts and operations as a public company; ● develop manufacturing capabilities for bulk materials and manufacture commercial quantities of product candidates at acceptable cost levels; ● achieve broad market acceptance of our product candidates in the medical community and with third- party payors and consumers; ● attract and retain an experienced management and advisory team; **38** ● successfully launch commercial sales of our products, whether alone or in collaboration with others; and ● maintain, expand and protect our intellectual property portfolio. Because of the numerous risks and uncertainties associated with development and manufacturing, we are unable to predict if we will generate revenue. If we cannot successfully execute on any of the factors listed above, our business may not succeed, we may never generate revenue and your investment will be adversely affected. ~~34We~~ **We** have identified material weaknesses in our internal controls **in the past** , and we cannot provide assurances ~~that these weaknesses will be effectively remediated or~~ that additional material weaknesses will not occur in the futureIf our internal control over financial reporting or our disclosure controls and procedures are not effective, we may not be able to accurately report our financial results, prevent fraud, or file our periodic reports in a timely manner, which may cause investors to lose confidence in our reported financial information and may lead to a decline in our stock price. Our management is responsible for establishing and maintaining adequate internal control over our financial reporting, as defined in Rule 13a- 15 (f) under the Exchange Act. Based on our assessment, we have concluded that **as of December 31, 2024 we have remediated our prior weakness over internal controls. During 2023 and the first three quarters of 2024,** we did not maintain effective review controls at a sufficient level of precision with certain financial statement areas and over unusual transactions involving complex accounting and related ~~.~~disclosure requirements. We also did not maintain effective information technology general controls over user access, program change management, and segregation of duties, within certain key information systems supporting **our** ~~the Company' s~~ accounting and financial reporting processes. Additionally, many of our business process controls dependent upon the information derived from these information systems were also ineffective, as we did not design and implement controls to validate the completeness and accuracy of underlying data utilized in the operation of those controls. While we **have** ~~plan to take~~ **taken** remedial action to address the material weaknesses **and we now believe that our internal control over financial reporting is effective** , we cannot provide any assurance that such remedial measures, or any other remedial measures we take, will **continue to** be effective. If we fail to maintain effective internal control over financial reporting, we may not be able to accurately report our financial results, detect or prevent fraud, or file our periodic reports in a timely manner, which may, among other adverse consequences, cause investors to lose confidence in our reported financial information and lead to a decline in our stock price. In addition, a material weakness will not be

considered remediated until the applicable controls operate for a sufficient period of time and management has concluded, through testing, that these controls are designed and operating effectively. Although management believes that the material weaknesses ~~will be~~ **have been** remediated ~~by the end of the fiscal year~~ there can be no assurance that ~~the deficiencies will be remediated at such time or~~ **our** ~~that the~~ internal control over financial reporting, as modified, will enable us to identify or avoid material weaknesses in the future. We expect to seek to raise additional capital in the future, which may be dilutive to stockholders or impose operational restrictions. We expect to seek to raise additional capital in the future to help fund development of our proposed products. If we raise additional capital through the issuance of equity or of debt securities, the percentage ownership of our current stockholders will be reduced. We may also enter into strategic transactions, issue equity as consideration for acquisitions or part of license issue fees to our licensors, compensate consultants or settle outstanding payables using equity that may be dilutive. We are authorized to issue 350, 000, 000 shares of ~~common~~ **Common** ~~stock~~ **Stock**, of which ~~17~~ **2**, ~~148~~ **782**, ~~049~~ **449** shares of ~~common~~ **Common** ~~stock~~ **Stock** were outstanding as of ~~December 31~~ **March 4**, ~~2023~~ **2025**. ~~At December 31, 2023, we had reserved 6, 834, 797 shares of common stock for issuance upon exercise of our outstanding options, and preferred shares. In addition, at such date, we had 2, 822, 845 shares of our common stock reserved for future issuance under our equity incentive plans~~. If all of ~~these~~ -- **the** ~~securities~~ **unissued authorized shares** were ~~to~~ **issued stockholders ownership percentage will** be **diluted** ~~exercised, the total number of shares of our common stock that we would be required to issue is 9, 657, 642, which in addition to the 17, 148, 049 shares outstanding, would leave 323, 194, 309 authorized but unissued shares of common stock available to be issued~~. In order to raise additional capital, we may in the future offer additional shares of our ~~common~~ **Common** ~~stock~~ **Stock** or other securities convertible into or exchangeable for our ~~common~~ **Common** ~~stock~~ **Stock** at prices that may not be the same as the price per share paid by existing stockholders, thereby subjecting such stockholders to dilution. Our stockholders may experience additional dilution in net book value per share and any additional equity securities may have rights, preferences and privileges senior to those of the holders of our ~~common~~ **Common** ~~stock~~ **Stock**. We may sell shares or other securities in any other offering at a price per share that is less than the price per share paid by existing stockholders, and investors purchasing shares or other securities in the future could have rights superior to existing stockholders. The price per share at which we sell additional shares of our ~~common~~ **Common** ~~stock~~ **Stock**, or securities convertible or exchangeable into ~~common~~ **Common** ~~stock~~ **Stock**, in future transactions may be higher or lower than the price per share paid by existing stockholders. ~~35Our~~ **39Our** operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations or our guidance. Our quarterly and annual operating results may fluctuate significantly in the future, which makes it difficult for us to predict our future operating results. The VCN Purchase Agreement requires that we make certain cash payments to Grifols upon attainment of certain milestones, which payments may vary significantly from period to period and any such variance could cause a significant fluctuation in our operating results from one period to the next. From time to time, we may enter into collaboration agreements with other companies that include development funding and significant upfront and milestone payments and / or royalties, which may become an important source of our revenue. Accordingly, our revenue may depend on development funding and the achievement of development and clinical milestones under any potential future collaboration and license agreements and sales of our products, if approved. These upfront and milestone payments may vary significantly from period to period and any such variance could cause a significant fluctuation in our operating results from one period to the next. In addition, our manufacturing and clinical trial expenses, which are anticipated to be significant, may fluctuate significantly quarter to quarter based upon whether or not we are engaged in clinical trials or manufacturing our product candidates, and timing of our process development work. Furthermore, we measure compensation cost for stock- based awards made to employees at the grant date of the award, based on the fair value of the award as determined by our board of directors, and recognize the cost as an expense over the employee' s requisite service period. As the variables that we use as a basis for valuing these awards change over time, our underlying stock price and stock price volatility, the magnitude of the expense that we must recognize may vary significantly. Furthermore, our operating results may fluctuate due to a variety of other factors, many of which are outside of our control and may be difficult to predict, including the following: ● the timing and cost of, and level of investment in, research and development activities relating to current product candidates and any future product candidates, which will change from time to time; ● our ability to enroll patients in clinical trials and the timing of enrollment; ● the timing and cost of manufacturing our current product candidates and any future product candidates, which may vary depending on FDA guidelines and requirements, the quantity of production and the terms of our agreements with manufacturers; ● expenditures that we will or may incur to acquire or develop additional product candidates and technologies; ● the timing and outcomes of clinical studies or competing product candidates; ● changes in the competitive landscape of our industry, including consolidation among our competitors or partners; ● any delays in regulatory review or approval of our current product candidates or any of our future product candidates; ● the level of demand for our current product candidates and any future product candidates, should they receive approval, which may fluctuate significantly and be difficult to predict; ● the risk / benefit profile, cost and reimbursement policies with respect to our products candidates, if approved, and existing and potential future drugs that compete with our product candidates; ● competition from existing and potential future drugs that compete with our current product candidates or any of our future product candidates; ● our ability to commercialize our current product candidates or any future product candidate inside and outside of the United States, either independently or working with third parties; ● our ability to establish and maintain collaborations, licensing or other arrangements; ● our ability to adequately support future growth; ● potential unforeseen business disruptions that increase our costs or expenses; ~~36~~ **40** ● future accounting pronouncements or changes in our accounting policies; and ● the changing and volatile global economic environment. The cumulative effects of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period- to- period basis may not be meaningful. Investors should not rely on our past results as an indication of our future performance. This variability and unpredictability could also result in our

failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated revenue and / or earnings guidance we may provide. If our acquired intangible assets become impaired **in the future as was the case in 2024** , we may be required to record a significant charge to earnings. We regularly review acquired intangible assets for impairment when events or changes in circumstances indicate that the carrying value may not be recoverable. We test goodwill and indefinite- lived intangible assets for impairment at least annually. Factors that may be considered a change in circumstances, indicating that the carrying value of the intangible assets may not be recoverable, include: macroeconomic conditions, such as deterioration in general economic conditions; industry and market considerations, such as deterioration in the environment in which we operate; cost factors, such as increases in labor or other costs that have a negative effect on earnings and cash flows; our financial performance, such as negative or declining cash flows or a decline in actual or planned revenue or earnings compared with actual and projected results of relevant prior periods; other relevant entity- specific events, such as changes in management, key personnel, strategy, or customers; and sustained decreases in share price. RISKS RELATED TO OUR BUSINESSPrior to 2022 we had not conducted any ~~cancer~~ research and development activities **directed to cancer diagnosis, treatment or prevention** and there can be no assurance that we will successfully be able to do so. Prior to the VCN Acquisition, our focus was on the microbiome and our research and development was focused primarily on therapeutics for various microbiome related diseases. Upon the VCN Acquisition, our focus has shifted to the use of oncolytic viruses to treat cancer. Although, ~~our~~ members of **our** management and scientific / development teams have experience in ~~this field~~ **the research and development of cancer treatments** , we may not be successful as a company with such focus. In the past Oncolytic Viruses have experienced certain safety and efficacy challenges. Although current clinical trials of **OVs** ~~oncolytic virotherapies~~ have supported their role as a potential treatment for cancer, there is the risk of virus- related toxicities in vivo and possible transmission to patients' contacts, such as other patients and health care workers. In recent years, clinical trials to address these concerns have been conducted. Any such transmission by VCN- 01 or a competitor would have an adverse impact on our future OV research and development efforts. Likewise, a number of **OVs** ~~oncolytic virotherapies~~ have previously failed to meet their primary endpoints in advanced clinical trials, potentially reducing investor and partner interest or confidence in the development of new such therapies, however well differentiated they are from previous products. Our research and development efforts may not result in commercially successful products and technologies, which may limit our ability to achieve profitability. We must continue to explore opportunities that may lead to new products and technologies. To accomplish this, we must commit substantial efforts, funds, and other resources to research and development. A high rate of failure is inherent in the research and development of new products and technologies. Any such expenditures that we make will be made without any assurance that our efforts will be successful. Failure can occur at any point in the process, including after significant funds have been invested. ~~37The~~ **41The** success of our business currently depends on our development, approval and commercialization of our lead product candidate, VCN- 01. Our ongoing Phase 1b / 2a clinical trial of SYN- 004 for the prevention of aGVHD in allogeneic HCT recipients, our completed Phase 1 single ascending and multiple ascending dose studies of SYN- 020 and ongoing early- stage clinical trials of VCN- 01 are not designed as registrational clinical trials and we currently do not have the necessary funding to complete any late stage registrational clinical trials. There are many uncertainties known and unknown that may affect the outcome of future clinical trials. All of our product candidates, including VCN- 01, SYN- 004 (ribaxamase), and SYN- 020 will require additional clinical and non- clinical development, regulatory review and approval in multiple jurisdictions, substantial investment, access to sufficient commercial manufacturing capacity and significant marketing efforts before we can generate any revenue from product sales. Regardless of whether our clinical trials are deemed to be successful, promising new product candidates may fail to reach the market or may only have limited commercial success because of efficacy or safety concerns, failure to achieve positive clinical outcomes, inability to obtain necessary regulatory approvals or satisfy regulatory criteria, limited scope of approved uses, excessive costs to manufacture, the failure to establish or maintain intellectual property rights, or infringement of the intellectual property rights of others. Failure to obtain regulatory approvals of VCN- 01, SYN- 004 (ribaxamase) or SYN- 020 in a timely manner would have a material adverse impact on our business. Even if we successfully develop VCN- 01, SYN- 004 (ribaxamase), SYN- 020 or other new products or enhancements, they may be quickly rendered obsolete by changing customer preferences, changing industry standards, or competitors' innovations. Innovations may not be quickly accepted in the marketplace because of, among other things, entrenched patterns of clinical practice or uncertainty over third- party reimbursement. We cannot state with certainty when or whether any of our products under development will be launched, whether we will be able to develop, license, or otherwise acquire drug candidates or products, or whether any products will be commercially successful. Failure to launch successful new products or new indications for existing products may cause our products to become obsolete, which may limit our ability to achieve profitability. We may form or seek strategic alliances or enter into additional licensing arrangements in the future, and we may not realize the benefits of such alliances or licensing arrangements. We may form or seek strategic alliances, create 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 our product candidates and any future product candidates that we may develop. Any of these relationships may require us to incur non- recurring and other charges, increase our near and long- term expenditures, issue securities that dilute our existing stockholders or disrupt our management and business. In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process is time- consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our product candidates because they may be deemed to be at too early ~~of~~ a stage of development for collaborative effort and third parties may not view our product candidates as having the requisite potential to demonstrate safety

and efficacy. If we license 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 and company culture. We cannot be certain that, following a strategic transaction or license, we will achieve the revenue or specific net income that justifies such transaction. Any delays in entering into new strategic partnership agreements related to our product candidates could delay the development and commercialization of our product candidates in certain geographies for certain indications, which would harm our business prospects, financial condition and results of operations. ~~38We~~ **42We** rely on licenses to use various technologies that are material to our business and we may not be able to retain rights licensed to us by others to commercialize key products and may not be able to establish or maintain the relationships we need to develop, manufacture, and market our products. In addition to our own patent applications, we also currently rely on licensing agreements with third party patent holders / licensors for our products. We have entered license agreements upon which our OV technology is dependent. If we breach the terms of any of our license agreements or collaborations, including any failure to make royalty payments required thereunder or failure to reach certain developmental milestones or fulfill our obligations under the agreements could result in a termination of the agreements. The Technology Transfer Agreement ") between VCN and IDIBELL for the exclusive license of the right to use a Spanish patent number P200901201 titled " Oncolytic adenoviruses for treating cancer " provides IDIBELL with the right to revoke the license if VCN ceases business activities for a continuous year or ceases to utilize the technology subject of the Technology Transfer Agreement, uses the technology in violation of the principals of IDIBELL or ICO or stops maintaining the patent licensed under the Technology Transfer Agreement. The ICO License provides that VCN and its sublicensees have an obligation to use all diligent and commercially reasonable efforts for the exploitation of the patent, otherwise, ICO may proceed to recover the license. The " IDIBELL / ICO License Agreement provides that the licensors have the right to revoke the IDIBELL / ICO License Agreement if VCN during a continuous period of two years abandons its research or development activities of the licensed patent or activities aimed at exploitation of the resulting products. ~~We entered into an option agreement with MGH to enter into an exclusive license to intellectual property and technology related to the use of IAP to maintain GI and microbiome health, diminish systemic inflammation, and treat age- related diseases. There can be no assurance that we will be able to reach agreement on license terms or that the terms will be favorable to us. This license agreement is expected to require us to meet certain diligence requirements and timelines in order to keep the license agreement in effect. In addition, certain license agreements, including the one that may potentially be entered into with MGH, typically contain provisions requiring royalty free non- exclusive licenses to the U. S government if any federal funding was used to invent any of the patents being licensed. In the event we or our sublicensee are not able to meet our diligence requirements contained in the license agreement with MGH or any other license agreement, we may not be able to retain the rights granted under our agreement or renegotiate with our arrangement institution on reasonable terms, or at all.~~ If any license were to terminate and we were to lose the right to commercialize our products, our business opportunity would be adversely affected. Furthermore, we currently have very limited product development capabilities, and limited marketing or sales capabilities. For us to research, develop, and test our product candidates, we would need to contract with outside researchers, in most cases those parties that did the original research and from whom we have licensed the technologies ~~. Our agreement with UT Austin allows UT Austin to terminate its agreement if we fail to comply with the terms of the agreement~~ . We can give no assurances that any of our issued patents licensed to us or any of our other patent applications will provide us with significant proprietary protection or be of commercial benefit to us. Furthermore, the issuance of a patent is not conclusive as to its validity or enforceability, nor does the issuance of a patent provide the patent holder with freedom to operate without infringing the patent rights of others. We may incur additional expenses in connection with our licenses and collaboration arrangements and our development of our product candidates. VCN' s collaboration agreements require that Theriva Biologics S. L. engage in certain research and development activities that require additional expenditures. Our ~~agreements~~ **agreement** with Washington University ~~and MGH~~ may require that we initiate certain studies and file or have accepted an NDA within a certain amount of time, each of which are costly and will require additional expenditures. Although all manufacturing, preclinical studies and human clinical trials are expensive and difficult to design and implement, costs associated with the manufacturing, research and development of biologic product candidates are generally greater in comparison to small molecule product candidates. Due to our small work force, we expect in future years to require additional personnel to support our later stage research and development efforts. Manufacturing of VCN- 01, SYN- 004 (ribaxamase) and SYN- 020 to support potential future clinical studies will require us to incur additional expenses. Because development activities in our collaborations are sometimes determined pursuant to joint steering committees, future development costs associated with these programs may be difficult to anticipate and may exceed our expectations. Our actual cash requirements may vary materially from our current expectations for a number of other factors that may include, but are not limited to, unanticipated technical challenges, enrollment challenges, changes in the focus and direction of our development activities or adjustments necessitated by changes in the competitive landscape in which we operate. If we are unable to continue to financially support such collaborations due to our own working capital constraints, we may be forced to delay our activities. If we are unable to obtain additional financing on terms acceptable to us or at all, we may be forced to seek licensing partners or discontinue development. ~~39Developments~~ **43Developments** by competitors may render our products or technologies obsolete or non- competitive. The pharmaceutical and biotechnology industries, including the oncolytic virus industry and the monoclonal antibody industry, are characterized by rapidly evolving technology and intense competition. Our competitors include major multi- national pharmaceutical companies and biotechnology companies developing both generic and proprietary therapies to treat serious diseases. Many of our competitors have drugs that have already been commercialized and therefore benefit from being first to market their products. Many of these companies are well- established and possess technical, human, research and development, financial, and sales and marketing resources significantly greater than ours. In addition, many of our potential competitors have formed strategic collaborations, partnerships and other types of joint ventures with larger, well established industry competitors that afford these companies' potential research and development and commercialization

advantages in the therapeutic areas we are currently pursuing. Academic research centers, governmental agencies and other public and private research organizations are also conducting and financing research activities which may produce products directly competitive to those being developed by us. In addition, many of these competitors may be able to obtain patent protection, obtain FDA and other regulatory approvals and begin commercial sales of their products before us, including for different indications of the same active ingredients that comprise our pipeline products. These competitors will compete with us in product sales as well as recruitment and retention of qualified scientific and management personnel, establishment of clinical trial sites and patient enrollment for clinical trials, as well as in the acquisition of technologies and technology licenses complementary to our programs or advantageous to our business. Companies pursuing clinical development of modified oncolytic adenoviruses include AdCure Bio LLC, Calidi Biotherapeutics, Inc., Candel Therapeutics, Inc., CG Oncology, Inc., Elicera Therapeutics AB, EpicentRx, Inc., GeneMedicine, Co Ltd., IconOVir Bio, Inc., Lokon Pharma AB, Memgen, Inc., Multivir, Inc., NewGenPharm Incorporation, Oncolys BioPharma, Inc., Orca Therapeutics B. V., Akamis Bio Ltd. (formerly PsiOxus Therapeutics Ltd), Shanghai Sunway Biotech Co., Ltd, Circio Holding ASA (formerly Targovax Oy | Targovax ASA), Tessa Therapeutics, Theolytics Ltd., TILT Biotherapeutics, Ltd., and Valo Therapeutics Oy. OV products have been or are being developed using other virus backbones, including: arenavirus (Hookipa Pharma, Inc.); Coxsackie virus (Viralytics Ltd., Oncorus Inc.); herpes simplex virus (Amgen, Inc., Candel Therapeutics, Inc., Daiichi Sankyo Company Ltd., Replimune, Inc., Takara Bio, Inc., Treovir LLC, Virogin Biotech, Inc., Wuhan Binhui Biotechnology Co., Ltd.); Maraba virus (Turnstone Biologics, Inc.); measles virus (Themis Biosciences GmbH, Vyriad, Inc.); myxoma virus (OncoMyx Therapeutics, Inc.); parvovirus (Oryx GmbH & Co. KG), reovirus (Oncolytics Biotech, Inc.); Seneca Valley virus (Seneca Therapeutics Inc., Oncorus Inc.); vesicular stomatitis virus (Boehringer Ingelheim, Cytonus Therapeutics, Inc., Vyriad, Inc.); and vaccinia viruses (Genelux Corporation, Imugene Ltd, Joint Biosciences Ltd, KaliVir Immunotherapeutics LLC, SillaJen, Inc., Transgene SA, Turnstone Biologics, Corp.). In addition, academic research centers may develop technologies that compete with our VCN- 01, SYN- 004 and SYN- 020, products and our other technologies. Should clinicians or regulatory authorities view alternative therapeutic regiments as more effective than our products, this might delay or prevent us from obtaining regulatory approval for our products, or it might prevent us from obtaining favorable reimbursement rates from payers, such as Medicare, Medicaid, hospitals and private insurers. Not only do our product candidates compete with other product candidates being developed for similar or the same indications, we also compete for employees **, ~~and for~~** clinical trial sites **, and participants in clinical trials** . We may seek to selectively establish collaborations, and, if we are unable to establish them on commercially reasonable terms, we may have to alter our development and commercialization plans. Our product development programs and the potential commercialization of our clinical product candidates will require substantial additional cash to fund expenses. For some of our product candidates, we may decide to collaborate with governmental entities or additional pharmaceutical and biotechnology companies for the development and potential commercialization of our product candidates. We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator' s resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator' s evaluation of a number of factors. Those factors may include the design or results of 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 for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with our product candidate. ~~40If~~ **44If** the parties we depend on for supplying substance raw materials for our product candidates and certain manufacturing- related services do not timely supply these products and services in sufficient quality or quantity, or if current drug supply becomes unusable, it may delay or impair our ability to develop, manufacture and market our product candidates. We rely on suppliers for the substance raw materials of our product candidates and third parties for manufacturing- related services to produce material that meets appropriate content, quality and stability standards and use in clinical trials of our products and, after approval, for commercial distribution. To succeed, clinical trials require adequate supplies of study material, which may be difficult or uneconomical to procure or manufacture and there can be no assurance that we will successfully procure such study material or even if procured, that we can do so in quantities and in a timely manner to allow our clinical trials to proceed as planned. Drug supply, once produced, is stored at clinical trial sites and vendor depots and we rely on these locations to maintain and protect the drug supply appropriately. Moreover, clinical drug supply has a finite shelf- life that may not be fully established prior to initiating early- stage clinical trials. We and our suppliers and vendors may not be able to (i) produce our study material to appropriate standards for use in clinical studies, (ii) perform under any definitive manufacturing, supply or service agreements with us, or (iii) remain in business for a sufficient time to successfully produce and market our product candidates, or (iv) prevent the drug supply from becoming unusable due to damage, loss or shelf- life expiration. If we do not maintain important manufacturing and service relationships, we may fail to find a replacement supplier or required vendor or manufacturer which could delay or impair our ability to conduct clinical trials and obtain regulatory approval for our products and substantially increase our costs or deplete profit margins, if any. If we do find replacement manufacturers and vendors, we may not be able to enter into agreements with them on terms and conditions favorable to us and there could be a substantial delay before a new facility could be qualified and registered with the FDA and foreign regulatory authorities. The third- party manufacturers of the active pharmaceutical ingredient (API) and drug product for our lead product candidates, VCN- 01, SYN- 004 (ribaxamase) and SYN- 020, are established cGMP manufacturers. For all other therapeutic areas, we have not yet established cGMP manufacturers for our biologic and drug candidates. We have used only one API manufacturer for each of our product candidates (VCN- 01, SYN- 004 or SYN- 020) used in clinical trials to date. Although we believe additional

manufacturers are available, if any of our manufacturers were to limit or terminate production or otherwise fail to meet the quality or delivery requirements needed to satisfy the supply commitments, the process of locating and qualifying alternate sources could require up to several months, during which time our production could be delayed. Any curtailment in the availability of ~~VCN- 01, SYN- 004 (ribaxamase) or~~ **our product candidates** ~~SYN- 020~~ could have a material adverse effect on our business, financial position and results of operations. In addition, because regulatory authorities must generally approve raw material sources for pharmaceutical products, changes in raw material suppliers may result in production delays or higher raw material costs. The manufacture of our product candidates requires significant expertise and manufacturers may encounter difficulties in production, particularly in scaling up production. These problems include difficulties with production costs and yields, quality control, including stability of the product and quality assurance testing, shortages of qualified personnel, as well as compliance with federal, state and foreign regulations. We may experience longer than expected lead times with respect to the manufacture of clinical drug supply, which may result from the increase in manufacturing scale necessary to conduct our anticipated late- stage clinical trials and result in trial delays. Furthermore, during the COVID- 19 pandemic, many manufacturers prioritized the manufacture of COVID- 19 related products, increasing the manufacturing lead times for non-COVID- 19 related products. If a pandemic should occur again and manufacturers prioritized the manufacture of pandemic related products, we may suffer a delay or interruption in the supply of clinical trial supplies. In addition, any **future pandemic or other disruption to clinical trial participation or the production of clinical trial materials** could delay the completion of our clinical trials, increase the costs associated with conducting our clinical trials and, depending upon the period of delay, require us to commence new clinical trials at significant additional expense or to terminate a clinical trial. We are responsible for ensuring that each of our contract manufacturers comply with the cGMP requirements of the FDA and other regulatory authorities from which we seek to obtain product approval. While we oversee compliance, we do not have control over our manufacturers and their compliance with regulatory requirements. These requirements include, among other things, quality control, quality assurance and the maintenance of records and documentation. The approval process for NDAs includes a review of the manufacturer' s compliance with cGMP requirements. We are responsible for regularly assessing a contract manufacturer' s compliance with cGMP requirements through record reviews and periodic audits and for ensuring that the contract manufacturer takes responsibility and corrective action for any identified deviations. A failure to comply with these requirements may result in fines and civil penalties, suspension of production, suspension or delay in product approval, product seizure or recall, or withdrawal of product approval. Furthermore, if our manufacturers fail to deliver the required commercial quantities on a timely basis and at commercially reasonable prices, we may be unable to meet demand for any approved products and would lose potential revenues. ~~41For~~ **45For** our Phase 2 clinical trial of VCN- 01 in patients with PDAC, we are administering our clinical product candidate, VCN- 01, in combination with other approved standard of care drugs. Any problems obtaining the standard of care drugs could result in a delay or interruption in our clinical trials. For our ~~planned~~ **ongoing** Phase 2 clinical trial of VCN- 01 in patients with PDAC, we are administering VCN- 01 in combination with the already approved standard of care drugs, gemcitabine / nab- paclitaxel, for which there has recently been a supply shortage. Therefore, our success will be dependent upon the continued use of and ability to obtain the standard of care drugs. We expect that in any other clinical trials we conduct for additional indications, our clinical product candidate will also be administered in combination with drugs owned by third parties. If any of the standard of care or third- party drugs that are used in our clinical trials are unavailable while the trials are continuing, the timeliness and commercialization costs could be impacted. In addition, if any of these other drugs are determined to have safety or efficacy problems, our clinical trials and commercialization efforts would be adversely affected. If third- party vendors, upon whom we rely to conduct our preclinical studies or clinical trials, do not perform or fail to comply with strict regulations, these studies or trials may be delayed, terminated, or fail, or we could incur significant additional expenses, which could materially harm our business. We have limited resources dedicated to designing, conducting and managing our preclinical studies and clinical trials. We rely on, third parties, including **clinical research organizations (** CROs **)** , consultants and principal investigators, to assist us in designing, managing, conducting, monitoring and analyzing the data from our preclinical studies and clinical trials. We rely on these vendors and individuals to perform many facets of the clinical development process on our behalf, including conducting preclinical studies, the recruitment of sites and subjects for participation in our clinical trials, maintenance of good relations with the clinical sites, and ensuring that these sites are conducting our trials in compliance with the trial protocol and applicable regulations. If these third parties fail to perform satisfactorily, or do not adequately fulfill their obligations under the terms of our agreements with them, we may not be able to enter into alternative arrangements without undue delay or additional expenditures, and therefore the preclinical studies and clinical trials of our clinical product candidates may be delayed or prove unsuccessful. Further, the FDA, the EMA, or similar regulatory authorities in other countries, may inspect some of the clinical sites participating in our clinical trials or our third-party vendors' sites to determine if our clinical trials are being conducted according to good clinical practices, or GCPs, or similar regulations. If we or a regulatory authority determine that our third- party vendors are not in compliance with, or have not conducted our clinical trials according to applicable regulations, we may be forced to exclude certain data from the results of the trial, or delay, repeat or terminate such clinical trials. We may fail to retain or recruit necessary personnel, and we may be unable to secure the services of consultants. As of March ~~30~~ **6** , ~~2024~~ **2025** , we employed ~~21~~ **20** full **- time employees and 2 part** - time employees, including employees located at Theriva Biologics' offices in Barcelona, Spain. We have also engaged clinical consultants to advise us on our clinical programs and regulatory consultants to advise us on our dealings with the FDA and other foreign regulatory authorities. Due to our small work force, we expect in future years to require additional personnel to support our later stage research and development efforts. We have been and may be required to retain additional consultants and employees in order to fulfill our obligations under our licenses and collaborations for our development of VCN- 01, SYN- 004 (ribaxamase), SYN- 020, and our agreements with Washington University and other collaborators. Our future performance will depend in part on our ability to successfully integrate newly hired officers into our management team and our ability to develop

an effective working relationship among senior management. Certain of our directors, scientific advisors, and consultants serve as officers, directors, scientific advisors, or consultants of other biopharmaceutical or biotechnology companies that might be developing competitive products to ours. Other than corporate opportunities, none of our directors are obligated under any agreement or understanding with us to make any additional products or technologies available to us. Similarly, we can give no assurances, and we do not expect and stockholders should not expect, that any biomedical or pharmaceutical product or technology identified by any of our directors or affiliates in the future would be made available to us other than corporate opportunities. We can give no assurances that any such other companies will not have interests that are in conflict with our interests. Losing key personnel or failing to recruit necessary additional personnel would impede our ability to attain our development objectives. There is intense competition for qualified personnel in the drug and biologic development areas, and we may not be able to attract and retain the qualified personnel we would need to develop our business. ~~42We~~ **46We** rely on independent organizations, advisors, and consultants to perform certain services for us, including handling substantially all aspects of regulatory approval, clinical management, manufacturing, marketing, and sales. We expect that this will continue to be the case. Such services may not always be available to us on a timely basis when we need them. Global health crises may adversely affect our planned operations. Our business and the business of the supplier of our clinical product candidates and the suppliers of the standard of care drugs that are administered in combination with our product candidates could be materially and adversely affected by the risks, or the public perception of the risks, related to a pandemic or other health crisis, such ~~as the recent outbreak of~~ COVID- 19. We ~~have~~ experienced delays in patient enrollment due to the COVID- 19 pandemic. **If** ~~To date, we are on track to meet all of our previously announced future clinical milestones; however, if the COVID- 19 pandemic increases in severity or~~ we should experience another pandemic, we could once again experience delays in patient enrollment and experience significant disruptions to our clinical development timelines. If we experience delays in patient enrollment or patients drop outs and we deem it necessary or advisable to improve patient recruitment by, among other things, opening additional clinical sites, we could incur increased clinical program expenses. Any such disruptions or delays would, and any such increased clinical program expenses could, adversely affect our business, financial condition, results of operations and growth prospects. In addition to delays or difficulties in enrolling patients in our clinical trials, we could experience the following disruptions that could severely impact our business and clinical trials, including: ● unwillingness of potential study participants to enroll in new clinical trials and / or visit healthcare facilities; ● postponement of enrollment in our clinical studies; ● diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials; ● interruption of key clinical trial activities, such as clinical site visits by study participants and clinical trial site monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others; ● limitations in employee resources that would otherwise be focused on the conduct of our clinical trials, including because of sickness of employees or their families, the desire of employees to avoid contact with large groups of people, or substantial numbers of resignations; ● delays in receiving approval from local regulatory authorities to initiate our planned clinical trials; ● delays in clinical site initiation due to understaffing in departments required for contracting and study start- up; ● delays in clinical sites receiving the supplies and materials needed to conduct our clinical trials; ● interruption in global shipping that may affect the manufacture and transport of clinical trial materials, such as investigational drug product used in our clinical trials; ● changes in local regulations as part of a response to the **a pandemic** ~~COVID- 19 coronavirus~~ outbreak which may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or to discontinue the clinical trials altogether; ● delays in necessary interactions with local regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees; and ● delay in the timing of interactions with the FDA and other regulatory agencies due to absenteeism by employees or by the diversion of their efforts and attention to approval of other therapeutics or other **pandemic- related** activities ~~related to COVID- 19~~ . ~~43In~~ **47In** addition, a significant outbreak of contagious diseases in the human population could result in the complete or partial closure of one or more manufacturing facilities which could impact our supply of our product candidates or the standard of care drugs that are administered in combination with our product candidates. In addition, an outbreak near where our clinical trial sites are located, has in the past, and may in the future impact our ability to recruit patients, and would likely delay our clinical trials, and could affect our ability to complete our clinical trials within the planned time periods. In addition, it could impact economies and financial markets, resulting in an economic downturn that could impact our ability to raise capital or slow down potential partnering relationships. Our business and the business of the suppliers of our clinical product candidates has been and is expected to continue to be materially and adversely affected by the pandemic and post- pandemic workforce and supply- chain issues. While we are currently not experiencing material delays, such events could result in the delay or complete or partial closure of clinical trial sites or one or more manufacturing facilities which could impact our supply of our clinical product candidates. In addition, it could impact economies and financial markets, resulting in an economic downturn that could impact our ability to raise capital or slow down potential partnering relationships. In addition, the outbreak of a pandemic could disrupt our operations due to absenteeism by infected or ill members of management or other employees, or absenteeism by members of management and other employees who elect not to come to work due to the illness affecting others in our office, or due to quarantines. Pandemics could also impact members of our Board of Directors resulting in absenteeism from meetings of the directors or committees of directors, and making it more difficult to convene the quorums of the full Board of Directors or its committees needed to conduct meetings for the management of our affairs. The extent to which ~~the virus~~ **a pandemic** may ~~continue to~~ impact our business and clinical trials will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the outbreak, travel restrictions and social distancing in the United States and Spain, business closures or business disruptions and the effectiveness of actions taken in the United States, Spain, and other countries to contain and treat the disease. We do not yet know the full extent of potential delays

or impacts on our business, operations, or the global economy as a whole. While the original spread of COVID- 19 has been mitigated, the continued emergence of novel virus strains mean there is no guarantee that a future outbreak of this or any other widespread epidemics will not occur, or that the global economy will recover, either of which could seriously harm our business. Business disruptions could seriously harm our future revenue and financial condition and increase costs and expenses. Our operations and those of our third- party suppliers and collaborators could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes or other extreme weather conditions, medical epidemics, labor disputes, war **, changes in national or regional laws, regulations and economic policies,** or other business interruptions. Any interruption could seriously harm our ability to timely proceed with any clinical programs or to supply product candidates for use in our clinical programs or during commercialization. For example, the COVID- 19 pandemic did, at points, cause an interruption in our clinical trial activities. Additionally, supply chain disruptions impacted and may continue to impact our research activities. **Continuing regional conflicts** ~~Moreover, at the end of 2021 and into 2022, tensions between the United States and Russia escalated when Russia amassed large numbers of military ground forces and support personnel on the Ukraine- Russia border and,~~ in ~~February 2022, Russia invaded Ukraine. In response, North Atlantic Treaty Organization, or NATO has deployed additional military forces to~~ Eastern Europe and the **Middle East** ~~Biden administration announced certain sanctions against Russia. The invasion of Ukraine and the retaliatory measures that have been taken, or could be taken in the future, by the United States, NATO, and other countries~~ have created global security concerns that could ~~result in a regional conflict and otherwise~~ have a lasting impact on regional and global economies, any or all of which could disrupt our supply chain, and despite the fact that we currently do not plan any clinical trials in Eastern Europe **or the Middle East** , may adversely impact the cost and conduct of our international clinical trials of our product candidates. Unfavorable U. S. or global economic conditions could adversely affect our business, financial condition or results of operations. Our results of operations could be adversely affected by general conditions in the global economy and financial markets. A severe or prolonged economic downturn could result in a variety of risks to our business, including weakened demand for our technologies and our ability to raise additional capital when needed on favorable terms, if at all. **Ongoing** ~~Recently, the rate of~~ inflation **in world** ~~has increased throughout the U. S. economy~~ **economies** ~~. Inflation~~ may adversely affect us by increasing the costs associated with performing research and development on internal research initiatives and partnered programs. We may experience significant increases in the prices of labor, consumables, and other costs of doing business. In an inflationary environment, such cost increases may outpace our expectations, causing us to use cash faster than forecasted. A weak or declining economy may also strain our partners, possibly resulting in supply disruption, or cause delays in their payments to us. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business. ~~44In~~ **48In** addition, the global macroeconomic environment could be negatively affected by, among other things, ~~COVID- 19 or other~~ pandemics or epidemics, instability in global economic markets, ~~increased U. S. trade tariffs and trade disputes with other countries,~~ instability in the global credit markets, supply chain weaknesses, instability in the geopolitical environment as a result of the withdrawal of the United Kingdom from the European Union, the Russian ~~invasion of~~ **war with** Ukraine, the war in the Middle East and other political tensions, and foreign governmental debt concerns. Such challenges have caused, and may continue to cause, uncertainty and instability in local economies and in global financial markets **. Changes in U. S. or international social, political, regulatory and economic conditions or in laws and policies governing trade, manufacturing, development and investment in the countries where we currently sell our products or conduct our business, could adversely affect our business, reputation, financial condition and results of operations. Changes or proposed changes in U. S. or other countries' trade policies may result in restrictions and economic disincentives on international trade. Tariffs, economic sanctions and other changes in U. S. trade policy have in the past and could in the future trigger retaliatory actions by affected countries, and certain foreign governments have instituted or are considering imposing retaliatory measures on certain U. S. goods. Further, any emerging protectionist or nationalist trends (whether regulatory- or consumer- driven) either in the United States or in other countries could affect the trade environment. We, like many other multinational corporations, conduct a significant amount of business that would be impacted by changes to the trade policies of the United States and foreign countries (including governmental action related to tariffs, international trade agreements, or economic sanctions). Such changes have the potential to adversely impact the U. S. economy or certain sectors thereof or the economy of another country in which we conduct operations, our industry and the global demand for our products, and as a result, could have a material adverse effect on our business, financial condition and results of operations** . We rely extensively on our information technology systems, and our systems and infrastructure face certain risks, including cybersecurity and data leakage risks. We rely on our information technology systems and infrastructure to process transactions, summarize results and manage our business, including maintaining client and supplier information. In the ordinary course of business, we collect, store and transmit large amounts of confidential information, and it is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information. Additionally, we utilize third parties, including cloud providers, to store, transfer and process data. Our information technology systems, as well as the systems of our suppliers and other partners, whose systems we do not control, are vulnerable to outages and an increasing risk of continually evolving deliberate intrusions to gain access to company sensitive information. The size and complexity of our information technology systems, and those of our third- party vendors with whom we contract, make such systems potentially vulnerable to service interruptions and security breaches from inadvertent or intentional actions by our employees, partners or vendors, from attacks by malicious third parties, or from intentional or accidental physical damage to our systems infrastructure maintained by us or by third parties. Data security incidents and breaches by employees and others with or without permitted access to our systems pose a risk that sensitive data may be exposed to unauthorized persons or to the public. Maintaining the secrecy of this confidential, proprietary, or trade secret information is important to our competitive business position. While we have taken steps to protect such information and invested in

information technology, there can be no assurance that our efforts will prevent service interruptions or security breaches in our systems or the unauthorized or inadvertent wrongful use or disclosure of confidential information that could adversely affect our business operations or result in the loss, dissemination, or misuse of critical or sensitive information. A cyber- attack or other significant disruption involving our information technology systems, or those of our vendors, suppliers and other partners, could also result in disruptions in critical systems, corruption or loss of data and theft of data, funds or intellectual property. A breach of our security measures or the accidental loss, inadvertent disclosure, unapproved dissemination, misappropriation or misuse of trade secrets, proprietary information, or other confidential information, whether as a result of theft, hacking, fraud, trickery or other forms of deception, or for any other reason, could enable others to produce competing products, use our proprietary technology or information, or adversely affect our business or financial condition. We may be unable to prevent outages or security breaches in our systems. We remain potentially vulnerable to additional known or yet unknown threats as, in some instances, we, our suppliers and our other partners may be unaware of an incident or its magnitude and effects. We also face the risk that we expose our vendors or partners to cybersecurity attacks. Any or all of the foregoing could adversely affect our results of operations and our business reputation. ~~Our~~ **49Our** business and operations would suffer in the event of computer system failures. Despite the implementation of security measures, our internal computer systems, and those of 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 over the internet, attachments to emails, persons inside our organization, or persons with access to systems inside our organization. The risk of a security breach or disruption, particularly through cyber- attacks or cyber- intrusions, 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. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our current or future product development programs. For example, the loss of clinical trial data from completed or any future 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. To the extent that any disruption or security breach was to result in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur material legal claims and liability, damage to our reputation, and the further development of our product candidates could be delayed. ~~45Any~~ -- **Any** failure to maintain the security of information relating to our patients, customers, employees and suppliers, whether as a result of cybersecurity attacks or otherwise, could expose us to litigation, government enforcement actions and costly response measures, and could disrupt our operations and harm our reputation. Significant disruptions to our information technology systems or breaches of information security could adversely affect our business. In connection with the pre- clinical and clinical development, sales and marketing of our products and services, we may from time to time transmit confidential information. We also have access to, collect or maintain private or confidential information regarding our clinical trials and the patients enrolled therein, employees, and suppliers, as well as our business. Although we have instituted security measures, there can be no assurance that these security measures will be able to protect against cyberattacks. Cyberattacks are rapidly evolving and becoming increasingly sophisticated. It is possible that computer hackers and others might compromise our security measures, or security measures of those parties that we do business with now or in the future, and obtain the personal information of patients in our clinical trials, vendors, employees and suppliers or our business information. A security breach of any kind, including physical or electronic break- ins, computer viruses and attacks by hackers, employees or others, could expose us to risks of data loss, litigation, government enforcement actions, regulatory penalties and costly response measures, and could seriously disrupt our operations. Any resulting negative publicity could significantly harm our reputation, which could cause us to lose market share and have an adverse effect on our results of operations. We may face particular data protection, data security and privacy risks in connection with the European Union' s Global Data Protection Regulation and other privacy regulations. Outside of the United States, the laws, regulations and standards in many jurisdictions apply broadly to the collection, use, and other processing of personal information. For example, in the European Union, the collection and use of personal data are governed by the provisions of the General Data Protection Regulation (the " GDPR "). The GDPR, together with national legislation, regulations and guidelines of the European Union. member states governing the processing of personal data, impose strict obligations on entities subject to the GDPR, including but not limited to: (i) accountability and transparency requirements, and enhanced requirements for obtaining valid consent from data subjects; (ii) obligations to consider data protection as any new products or services are developed and to limit the amount of personal data processed; (iii) obligations to comply with the data protection rights of data subjects; and (iv) obligations to report certain personal data breaches to governmental authorities and individuals. Data protection authorities from the different E. U. member states and other European countries may enforce the GDPR and national data protection laws differently, and introduce additional national regulations and guidelines, which adds to the complexity of processing European personal data. Failure to comply with the requirements of the GDPR and the related national data protection laws may result in significant monetary fines and other administrative penalties (the GDPR authorizes fines for certain violations of up to 4 % of global annual revenue or € 20 million, whichever is greater) as well as civil liability claims from individuals whose personal data was processed. Additionally, expenses associated with compliance could reduce our operating margins. The GDPR also prohibits the transfer of personal data from the E. U. to countries outside of the E. U. unless made to a country deemed by the European Commission to provide adequate protection for personal data or accomplished by means of an approved data transfer mechanism (e. g., standard contractual clauses). Data protection authority guidance and enforcement actions that restrict companies' ability to transfer data may increase risk relating to data transfers or make it more difficult or impossible to transfer E. U. personal data to the U. S. ~~46REGULATORY~~ **50REGULATORY** RISKS If we do not obtain the necessary regulatory approvals in the U. S. and / or other countries we will not be able to develop or sell our product candidates. We cannot assure you that we will receive the approvals necessary to commercialize any of our product candidates or any product candidates we acquire or develop in the future. We will need FDA approval to commercialize our

product candidates in the U. S. and approvals from the FDA- equivalent regulatory authorities in foreign jurisdictions to commercialize our product candidates in those jurisdictions. We will be required to conduct clinical trials that will be costly and we currently do not have the funding to complete any registrational clinical trials. We cannot predict whether our clinical trials will demonstrate the safety and efficacy of our product candidates or if the results of any clinical trials will be sufficient to advance to the next phase of development or for approval from the FDA (or equivalent foreign regulatory authorities). We also cannot predict whether our research and clinical approaches will result in drugs or therapeutics that the FDA considers safe and effective for the proposed indications. The FDA has substantial discretion in the drug approval process. The approval process may be delayed by changes in government regulation, future legislation or administrative action or changes in FDA policy that occur prior to or during our regulatory review. Delays in obtaining regulatory approvals may prevent or delay commercialization of, and our ability to derive product revenues from our product candidates; and diminish any competitive advantages that we may otherwise believe that we hold. Even if we comply with all FDA (or equivalent foreign regulatory authorities) requests, the FDA may ultimately reject one or more of our NDAs or BLAs. We may never obtain regulatory clearance for any of our product candidates. Failure to obtain FDA approval of any of our product candidates will severely undermine our business by leaving us without a saleable product, and therefore without any source of revenues, until another product candidate can be developed. There is no guarantee that we will ever be able to develop or acquire another product candidate. In addition, the FDA (or equivalent foreign regulatory authorities) may require us to conduct additional pre- clinical and clinical testing or to perform post- marketing studies, as a condition to granting marketing approval of a product. The results generated after approval could result in loss of marketing approval, changes in product labeling, and / or new or increased concerns about the side effects or efficacy of a product. The FDA has significant post- market authority, including the explicit authority to require post- market studies and clinical trials, labeling changes based on new safety information, and compliance with FDA- approved risk evaluation and mitigation strategies. The FDA' s exercise of its authority has in some cases resulted, and in the future could result, in delays or increased costs during product development, clinical trials and regulatory review, increased costs to comply with additional post- approval regulatory requirements and potential restrictions on sales of approved products. In foreign jurisdictions, we must also receive approval from the appropriate regulatory authorities before we can commercialize any products, which can be time consuming and costly. Foreign regulatory approval processes generally include all of the risks associated with the FDA approval procedures described above but processes, requirements and timelines for approval by these agencies may differ significantly from the FDA. There can be no assurance that we will receive the approvals necessary to commercialize our product candidate for sale outside the United States. If the FDA approves any of our product candidates, the labeling, manufacturing, packaging, adverse event reporting, storage, advertising, promotion and record- keeping for our products will be subject to ongoing FDA requirements and continued regulatory oversight and review. Our drug manufacturers and subcontractors that we retain will be required to comply with FDA and other regulations. We may also be subject to additional FDA post- marketing obligations. If we are not able to maintain regulatory compliance, we may not be permitted to market our product candidates and / or may be subject to product recalls, seizures, suspension of regulatory approval, suspension of production, injunctions or civil or criminal sanctions. The subsequent discovery of previously unknown problems with any marketed product, including adverse events of unanticipated severity or frequency, may result in restrictions on the marketing of the product, and could include withdrawal of the product from the market. ~~Clinical~~ **51Clinical** trials are very expensive, time-consuming, and difficult to design and implement. Human clinical trials are very expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. The clinical trial process is also time-consuming. We estimate that clinical trials for our product candidates would take at least several years to complete. Furthermore, failure can occur at any stage of the trials, and we could encounter problems that cause us to abandon or repeat clinical trials. Commencement and completion of clinical trials may be delayed by several factors, including: ● obtaining **permission to proceed under** an IND application with the FDA or foreign equivalent to commence clinical trials; ~~47~~ ● identification of, and acceptable arrangements with, one or more clinical sites; ● obtaining IRB or ~~EC~~ **IEC** approval to commence clinical trials; ● obtaining IBC approval for use of a genetically modified organism; ● unforeseen safety issues; ● determination of dosing; ● lack of effectiveness during clinical trials; ● slower than expected rates of patient recruitment; ● inability to monitor patients adequately during or after treatment; ● lower than expected rates of patient completion of clinical trials; ● inability to obtain supply of our drug candidate in a timely manner; ● inability or unwillingness of medical investigators to follow our clinical protocols; and ● unwillingness of the FDA or foreign equivalent, IRBs / ~~ECs~~ **IECs** , or IBCs to permit the clinical trials to be initiated. In addition, we, IRBs / ~~ECs~~ **IECs** or the FDA or foreign equivalent may suspend our clinical trials at any time if it appears that we are exposing participants to unacceptable health risks or if IRBs / ~~ECs~~ **IECs** or the FDA or foreign equivalent finds deficiencies in our submissions or conduct of our trials. ~~The~~ **52The** results of our clinical trials may not support our product candidate claims and the results of preclinical studies and completed clinical trials are not necessarily predictive of future results. To date, long- term safety and efficacy have not yet been demonstrated in clinical trials for any of our product candidates. Favorable results in our early studies or trials may not be repeated in later studies or trials as was the case with SYN- 010. Even if our clinical trials are initiated and completed as planned, we cannot be certain that the results will support our product candidate claims. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful. Success in Phase 1 studies of VCN- 01 in PDAC or retinoblastoma does not ensure success of VCN- 01, especially in light of the small number of patients treated in those trials. Success of our predecessor P1A clinical product or positive topline data from our previous SYN- 004 (ribaxamase) Phase 1 and Phase 2 clinical trials, does not ensure success of SYN- 004 (ribaxamase). Furthermore, the FDA could determine that VCN- 01 or SYN- 004 (ribaxamase) have not demonstrated appropriate safety and thus require additional clinical trials and safety data, despite prior positive clinical trial results. We cannot be sure that the results of later clinical trials would replicate the results of prior clinical trials and preclinical testing nor that they would satisfy the requirements of the FDA or other regulatory agencies. Clinical trials may fail to demonstrate that our product

candidates are safe for humans and effective for indicated uses. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unacceptable safety issues, notwithstanding promising results in earlier trials. Most product candidates that commence clinical trials are never approved as products. Any such failure could cause us or our sublicensee to abandon a product candidate and might delay development of other product candidates. Preclinical and clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals or commercialization. Any delay in, or termination of, our clinical trials would delay our obtaining FDA approval for the affected product candidate and, ultimately, our ability to commercialize that product candidate. ~~48Difficulties~~ **Difficulties** enrolling patients in our clinical trials or delays in enrollment are expected to result in our clinical development activities being delayed or otherwise adversely affected. Delays in patient enrollment may result in increased costs or may adversely affect timing or outcome of planned clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our product candidates. This can lead to delays in completion of clinical trials as well as additional expense for recruitment of patients. In addition, any pandemic may result in fewer clinical study personnel being available to conduct clinical testing for patients currently enrolled in our clinical trials. Patients who are administered our product candidates may experience unexpected side effects or other safety risks that could cause a halt in their clinical development, preclude approval of our product candidates or limit their commercial potential. Our clinical trials may be suspended at any time for a number of reasons. We may voluntarily suspend or terminate our clinical trials if at any time we believe that they present an unacceptable risk to the clinical trial subjects. In addition, the FDA or other regulatory agencies may order the temporary or permanent discontinuation of our clinical trials at any time if they believe that the clinical trials are not being conducted in accordance with applicable regulatory requirements or that they present an unacceptable safety risk to the clinical trial subjects. For example, the FDA or foreign equivalents could determine that VCN- 01 or SYN- 004 has not demonstrated appropriate safety, that adverse events are drug related and require additional clinical trials and safety data, despite positive results from Phase 1 clinical trials of VCN- 01 or our SYN- 004 Phase 2b clinical trial. Administering any product candidate to humans may produce undesirable side effects. These side effects could interrupt, delay or halt clinical trials of our product candidates and could result in the FDA or other regulatory authorities denying further development or approval of our product candidates for any or all targeted indications. Ultimately, some or all of our product candidates may prove to be unsafe for human use. Moreover, we could be subject to significant liability if any volunteer or patient suffers, or appears to suffer, adverse health effects as a result of participating in our clinical trials. Any of these events could prevent us from achieving or maintaining market acceptance of our product candidates and could substantially increase commercialization costs. ~~It~~ **53It** is possible that we may not be able to obtain or maintain orphan drug designation or exclusivity for our drug candidates, which could limit the potential profitability of our product candidates. Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs for the treatment or prevention of rare diseases or conditions with relatively small patient populations as orphan drugs. Under the Orphan Drug Act of 1983, the (“ Orphan Drug Act ”), the FDA may designate a product as an orphan drug if it is a drug intended to treat a rare disease or condition, which is defined as a patient population of fewer than 200, 000 individuals in the United States. We **have** received orphan drug designation from **both** the FDA **and EMA** for VCN- 01 for the treatment of retinoblastoma and ~~from the EMA~~ for the treatment of pancreatic cancer. If a product with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a seven- year period of marketing exclusivity **in the United States** , which precludes the FDA from approving another marketing application for the same drug for the same indication during that time period with some exceptions. A similar provision in the European Union allows 10 years of exclusivity in Europe. The European exclusivity period can be reduced to six years if a drug no longer meets the criteria for orphan drug designation or if the drug is sufficiently profitable so that marketing exclusivity is no longer justified. Orphan drug exclusivity may be lost in Europe under certain situations, such as the inability of the holder of the orphan drug designation to produce sufficient quantities of the drug to meet the needs of patients with the rare disease or condition or for certain other reasons. **Although we have been granted orphan drug designation for VCN- 01 for the treatment of retinoblastoma and pancreatic cancer, this does not mean FDA will approve the NDA. Even if we obtain FDA approval, we may not be able to obtain or maintain orphan drug exclusivity for VCN- 01. We may not be the first to obtain marketing approval of VCN- 01 designation for the orphan- designated indication due to the uncertainties associated with developing pharmaceutical products. In addition, exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan- designated indication or may be lost if the FDA later determines that the request for designation was materially defective or if we are unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition. Further, even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs with different active moieties may be approved for the same condition, or the competitive product is otherwise outside the scope of exclusivity. Even after an orphan drug is approved, the FDA can subsequently approve the same drug with the same active moiety for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care or the manufacturer of the product with orphan exclusivity is unable to maintain sufficient product quantity. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process, nor does it prevent competitors from obtaining approval of the same product candidate for indications other than those in which orphan drug designation have been granted. Fast Track designation by the FDA may not actually lead to a faster development or regulatory review or approval process, and does not assure FDA approval of our product candidate and, even if we obtain FDA approval, we may not receive marketing approval, marketing exclusivity or other expected benefits. In May 2024, the FDA granted Fast Track designation to VCN- 01 for the treatment of pancreatic cancer. However, the receipt of such a designation for a product**

candidate may not result in a faster development process, review or approval compared to drugs considered for approval under conventional regulatory procedures and does not assure that the product will ultimately be approved by the regulatory authority or that approval will be granted within any particular timeframe. As a result, while we have received Fast Track designation for VCN- 01 for the treatment of pancreatic cancer, we may not experience a faster development process, review or approval compared to conventional FDA procedures. In addition, the FDA may withdraw Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program. Fast Track designation alone does not guarantee qualification for the FDA' s priority review procedures. 54Although we have obtained rare pediatric disease designation for VCN- 01 for the treatment of retinoblastoma, we may not be eligible to receive a priority review voucher in the event the FDA determines we no longer meet the criteria for designation, revokes the designation or FDA approval of a BLA for VCN- 01 for retinoblastoma does not occur prior to September 30, 2026. The FDA grants rare pediatric disease designation for rare diseases (fewer than 200, 000 affected persons in the United States) that are serious and life- threatening and primarily affect children ages 18 years or younger. The sponsor of an application for a rare pediatric disease drug product may be eligible for a voucher that can be used or sold to obtain a priority review for a subsequent application submitted under section 505 (b) (1) of the FDCA or section 351 of the PHS Act. The rare pediatric disease priority review voucher program was most recently reauthorized by Congress through December 20, 2024, with the potential for priority review vouchers to be granted through September 30, 2026. We received rare pediatric disease designation from the FDA for VCN- 01 on July 30, 2024. Vouchers for rare pediatric disease drugs are awarded for qualifying applications when the drug receives approval. Although VCN- 01 has received rare pediatric disease designation for the treatment of retinoblastoma, VCN- 01 may not receive a priority review voucher for a number of reasons: VCN- 01 may not receive approval for retinoblastoma prior to September 30, 2026; VCN- 01 may receive approval in adults, but not pediatric patients; VCN- 01 may not meet the eligibility requirements for a priority voucher at the time we seek approval for VCN- 01. Finally, a rare pediatric disease designation does not necessarily lead to faster development or regulatory review of the product or increase the likelihood that it will receive marketing approval. The failure to maintain rare pediatric disease designation for VCN- 01 or if FDA approval does not occur prior to September 30, 2026 could result in the inability to receive a priority review voucher which could adversely affect our business, financial condition and results of operations. Our product candidates, if approved for sale, may not gain acceptance among physicians, patients and the medical community, thereby limiting our potential to generate revenues. If one of our product candidates is approved for commercial sale by the FDA or other regulatory authorities, the degree of market acceptance of any approved product by physicians, healthcare professionals and third- party payors and our profitability and growth will depend on a number of factors, including: ● demonstration of safety and efficacy; ● changes in the practice guidelines and the standard of care for the targeted indication; ● relative convenience and ease of administration; ● the prevalence and severity of any adverse side effects; ~~49~~ ● budget impact of adoption of our product on relevant drug formularies; ● the availability, cost and potential advantages of alternative treatments, including less expensive generic drugs; ● pricing, reimbursement and cost effectiveness, which may be subject to regulatory control; ● effectiveness of our or any of our partners' sales and marketing strategies; ● the product labeling or product insert required by the FDA or regulatory authority in other countries; and ● the availability of adequate third- party insurance coverage or reimbursement. ~~If~~ **55If** any product candidate that we develop ~~does~~ **is** not ~~provide a treatment regimen that is~~ as beneficial as, or is perceived as **not** being as beneficial as, the current standard of care or otherwise does not provide patient benefit, that product candidate, if approved for commercial sale by the FDA or other regulatory authorities, likely will not achieve market acceptance. Our ability to effectively promote and sell any approved products will also depend on pricing and cost- effectiveness, including our ability to produce a product at a competitive price and our ability to obtain sufficient third- party coverage or reimbursement. If any product candidate is approved but does not achieve an adequate level of acceptance by physicians, patients and third- party payors, our ability to generate revenues from that product would be substantially reduced. In addition, our efforts to educate the medical community and third- party payors on the benefits of our product candidates may require significant resources, may be constrained by FDA rules and policies on product promotion, and may never be successful. We depend on third parties, including researchers and sublicensees, who are not under our control. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to seek or obtain regulatory approval for or commercialize our product candidates. We depend on independent investigators and scientific collaborators, such as universities and medical institutions or private physician scientists, to advise us and to conduct our preclinical and clinical trials under agreements with us. These collaborators are not our employees and we cannot control the amount or timing of resources that they devote to our programs or the timing of their procurement of clinical- trial data or their compliance with applicable regulatory guidelines. Should any of these scientific inventors / advisors or those of our sublicensee become disabled or die unexpectedly, or should they fail to comply with applicable regulatory guidelines, we or our sublicensee may be forced to scale back or terminate development of that program. They may not assign as great a priority to our programs or pursue them as diligently as we would if we were undertaking those programs ourselves. Failing to devote sufficient time and resources to our drug- development programs, or substandard performance and failure to comply with regulatory guidelines, could result in delay of any FDA applications and our commercialization of the drug candidate involved. These collaborators may also have relationships with other commercial entities, some of which may compete with us. Our collaborators assisting our competitors could harm our competitive position. We have in the past, and expect to have in the future, agreements with third- party contract research organizations (CROs) under which we have delegated to the CROs the responsibility to coordinate and monitor the conduct of our VCN- 01, SYN- 004 and SYN- 020 clinical trials and to manage data for our clinical programs. We also rely upon CROs to monitor and manage data for our clinical programs, as well as the execution of future nonclinical studies. We expect to control only certain aspects of our CROs' activities. Nevertheless, we will be responsible for ensuring that

each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards and our reliance on the CROs does not relieve us of our regulatory responsibilities. ~~50Our~~ -- **Our** Phase 1b / 2a clinical trial of SYN-004, and Phase 1 and Phase 2 clinical trials for VCN- 01 are being conducted by clinical sites over which we have little direct control. We, our CROs and our clinical sites are required to comply with current Good Clinical Practices, or cGCPs, regulations and guidelines issued by the FDA and by similar governmental authorities in other countries where we are conducting clinical trials. We have an ongoing obligation to monitor the activities conducted by our CROs and at our clinical sites to confirm compliance with these requirements. In the future, if we, our CROs or our clinical sites fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA may require us to perform additional clinical trials before approving our marketing applications. In addition, our clinical trials must be conducted with product produced under cGMP regulations and will require a large number of test subjects. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. Our CROs are not our employees, and we do not control whether or not they devote sufficient time and resources to our future clinical and nonclinical programs. These CROs 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 which could harm our competitive position. We face the risk of potential unauthorized disclosure or misappropriation of our intellectual property by CROs, which may reduce our trade secret protection and allow our potential competitors to access and exploit our proprietary technology. If our CROs or investigator-sponsored clinical sites do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced, or if the quality or accuracy of the clinical data they obtain is compromised due to their failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase, and our ability to generate revenue could be delayed. ~~If~~ **56If** our relationship with these CROs terminate, we may not be able to enter into arrangements with alternative CROs or do so on commercially reasonable terms. Switching or adding additional CROs involves substantial cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we intend to carefully manage our relationships with our CROs, there can be no assurance that it will not encounter challenges or delays in the future or that these delays or challenges will not have an adverse impact on our business, financial condition and prospects. We currently have no marketing, sales or distribution organization and have no experience in marketing products as a company. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our product candidates, we may not be able to generate product revenue. We currently have no marketing, sales or distribution capabilities and have no experience in marketing products. We may develop an in- house marketing organization and sales force, which will require significant capital expenditures, management resources and time. We will have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain marketing and sales personnel. If we are unable **to** or decide not to **,** establish internal sales, marketing and distribution capabilities, we will pursue collaborative arrangements regarding the sales and marketing of our products; however, there can be no assurance that we will be able to establish or maintain such collaborative arrangements. Any revenue we receive will depend upon the efforts of such third parties, which may not be successful. We may have little or no control over the marketing and sales efforts of such third parties and our revenue from product sales may be lower than if we had commercialized our product candidates ourselves. We also face competition in our search for third parties to assist us with the sales and marketing efforts of our product candidates. There can be no assurance that we will be able to develop in- house sales and distribution capabilities or establish or maintain relationships with third- party collaborators to commercialize any product in the United States or overseas. Reimbursement may not be available for our product candidates, which would impede sales. Market acceptance and sales of our product candidates may depend on coverage and reimbursement policies and health care reform measures. Decisions about formulary coverage as well as levels at which government authorities and third- party payers, such as private health insurers and health maintenance organizations, reimburse patients for the price they pay for our products as well as levels at which these payors pay directly for our products, where applicable, could affect whether we are able to commercialize these products. We cannot be sure that reimbursement will be available for any of our products. Also, we cannot be sure that coverage or reimbursement amounts will not reduce the demand for, or the price of, our products. If coverage and reimbursement are not available or are available only at limited levels, we may not be able to commercialize our products. ~~51In~~ **In** recent years, officials have made numerous proposals to change the health care system in the United States. These proposals include measures that would limit or prohibit payments for certain medical treatments or subject the pricing of drugs to government control. In addition, in many foreign countries, particularly the countries of the European Union, the pricing of prescription drugs is subject to government control. If our products are or become subject to government regulation that limits or prohibits payment for our products, or that subjects the price of our products to governmental control, we may not be able to generate revenue, attain profitability or commercialize our products. As a result of legislative proposals and the trend towards managed health care in the United States, third- party payors are increasingly attempting to contain health care costs by limiting both coverage and the level of reimbursement of new drugs. They may also impose strict prior authorization requirements and / or refuse to provide any coverage of uses of approved products for medical indications other than those for which the FDA or foreign equivalent has granted market approvals. As a result, significant uncertainty exists as to whether and how much third- party payors will reimburse patients for their use of newly- approved drugs, which in turn will put pressure on the pricing of drugs. ~~Healthcare~~ **57Healthcare** reform measures could hinder or prevent our product candidates' commercial success. The U. S. government and other governments have shown significant interest in pursuing continued healthcare reform. Any government- adopted reform measures could adversely impact the pricing of healthcare products and services in the United States or internationally and the

amount of reimbursement available from governmental agencies or other third- party payors. The continuing efforts of the U. S. and foreign governments, insurance companies, managed care organizations and other payors of health care services to contain or reduce health care costs may adversely affect our ability to set prices for our products which we believe are fair, and our ability to generate revenues and achieve and maintain profitability. New laws, regulations and judicial decisions, or new interpretations of existing laws, regulations and decisions, that relate to healthcare availability, methods of delivery or payment for products and services, or sales, marketing or pricing, may limit our potential revenue, and we may need to revise our research and development programs. The pricing and reimbursement environment may change in the future and become more challenging due to several reasons, including policies advanced by the current executive administration in the United States, new healthcare legislation or fiscal challenges faced by government health administration authorities. Specifically, in both the United States and some foreign jurisdictions, there have been a number of legislative and regulatory proposals to change the health care system in ways that could affect our ability to sell our products profitably. If we fail to comply with state and federal healthcare regulatory laws, we could face substantial penalties, damages, fines, disgorgement, exclusion from participation in governmental healthcare programs, and the curtailment of operations, any of which could harm our business. Although we do not provide healthcare services or submit claims for third party reimbursement, we are subject to healthcare fraud and abuse regulation and enforcement by federal and state governments which could significantly impact our business. The laws that may affect our ability to operate include, but are not limited to: ● the federal anti- kickback statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering, or paying remuneration, directly or indirectly, in cash or in kind, in exchange for or to induce either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service for which payment may be made, in whole or in part, under federal healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of this statute or specific intent to violate it; ● the civil FCA, which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other third- party payors that are false or fraudulent; knowingly making using, or causing to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the government; or knowingly making, using, or causing to be made or used, a false record or statement to avoid, decrease or conceal an obligation to pay money to the federal government; ● the criminal FCA, which imposes criminal fines or imprisonment against individuals or entities who make or present a claim to the government knowing such claim to be false, fictitious or fraudulent; ● HIPAA, which created federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters; ~~52~~ ● the federal civil monetary penalties statute, which prohibits, among other things, the offering or giving of remuneration to a Medicare or Medicaid beneficiary that the person knows or should know is likely to influence the beneficiary' s selection of a particular supplier of items or services reimbursable by a Federal or state governmental program; ● the federal physician sunshine requirements under the ACA, which require certain manufacturers of drugs, devices, biologics, and medical supplies to report annually to the U. S. Department of Health and Human Services information related to payments and other transfers of value to physicians, other healthcare providers, and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members; ~~and~~ **and58** ● state and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws that may apply to items or services reimbursed by any third- party payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the device industry' s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; and state laws that require device manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures. Further, the ACA, among other things, amended the intent requirements of the federal anti- kickback statute and certain criminal statutes governing healthcare fraud. A person or entity can now be found guilty of violating the statute without actual knowledge of the statute or specific intent to violate it. In addition, the ACA provided that the government may assert that a claim including items or services resulting from a violation of the federal Anti- Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA. If a government authority were to conclude that we provide improper advice to our customers or encouraged the submission of false claims for reimbursement, we could face action against us by government authorities. Any violations of these laws, or any action against us for violation of these laws, even if we successfully defend against it, could result in a material adverse effect on our reputation, business, results of operations and financial condition. We have entered into consulting and scientific advisory board arrangements with physicians and other healthcare providers. Compensation for some of these arrangements includes the provision of stock options. While we have worked to structure our arrangements to comply with applicable laws, because of the complex and far- reaching nature of these laws, regulatory agencies may view these transactions as prohibited arrangements that must be restructured, or discontinued, or for which we could be subject to other significant penalties. We could be adversely affected if regulatory agencies interpret our financial relationships with providers who influence the ordering of and use our products to be in violation of applicable laws. The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have recently increased 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. Responding to investigations can be time- and resource- consuming and can divert management' s attention from the business. Additionally, as a result of these investigations, healthcare providers and entities may have to agree to additional onerous compliance and reporting requirements as part of a consent decree or corporate integrity agreement. Any such investigation or settlement could increase our costs or otherwise have an adverse effect on our business. If we obtain approval to commercialize our clinical product candidates outside of the United States, a variety of risks associated with international operations could harm our business. If our clinical product

candidate is approved for commercialization, we intend to enter into agreements with third parties to market them in certain jurisdictions outside the United States. We expect that we will be subject to additional risks related to international operations or entering into international business relationships, including: ● different regulatory requirements for drug approvals and rules governing drug commercialization in foreign countries; ● reduced protection for intellectual property rights; ● unexpected changes in tariffs, trade barriers and regulatory requirements; ● economic weakness, including inflation, or political instability in particular foreign economies and markets; ~~53~~ ● compliance with tax, employment, immigration and labor laws for employees living or traveling abroad; ● foreign reimbursement, pricing and insurance regimes; ● foreign taxes; **59** ● foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country; ● workforce uncertainty in countries where labor unrest is more common than in the United States; ● potential noncompliance with the U. S. Foreign Corrupt Practices Act of 1977, as amended, the U. K. Bribery Act 2010 and similar anti- bribery and anticorruption laws in other jurisdictions; ● product shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and ● business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires. We have no prior experience in these areas. In addition, there are complex regulatory, tax, labor and other legal requirements imposed by both the European Union and many of the individual countries in Europe with which we will need to comply. If product liability lawsuits are successfully brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates. We face an inherent risk of product liability lawsuits related to the testing of our product candidates and will face an even greater risk if we sell our product candidates commercially. Currently, we are not aware of any anticipated product liability claims with respect to our product candidates. In the future, an individual may bring a liability claim against us if one of our product candidates causes, or merely appears to have caused, an injury. If we cannot successfully defend ourselves against the product liability claim, we may incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in: ● decreased demand for our product candidates; ● injury to our reputation; ● withdrawal of clinical trial participants; ● costs of related litigation; ● initiation of investigations by regulators; ● substantial monetary awards to patients or other claimants; ● distraction of management' s attention from our primary business; ● product recalls; ● loss of revenue; and ● the inability to commercialize our product candidates. We have clinical trial liability insurance. We intend to expand our insurance coverage to include the sale of commercial products if marketing approval is obtained for our product candidates. Our current insurance coverage may prove insufficient to cover any liability claims brought against us. In addition, because of the increasing costs of insurance coverage, we may not be able to maintain insurance coverage at a reasonable cost or obtain insurance coverage that will be adequate to satisfy liabilities that may arise. ~~54INTELLECTUAL~~ **60INTELLECTUAL** PROPERTY RISKSWe rely on patents, patent applications, trade secrets and various regulatory exclusivities to protect some of our product candidates and our ability to compete may be limited or eliminated if we are not able to protect our products. The patent positions of pharmaceutical companies are uncertain and may involve complex legal and factual questions. The issuance, scope, validity, enforceability, and commercial value of our current or future patent rights are highly uncertain. We cannot be sure that patent coverage will issue, or will be maintained, to protect our products, in some or all relevant jurisdictions. Our patents may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. Even if patents do successfully issue and even if such patents cover our product candidates and extend for a commercially relevant time, third parties may initiate invalidity, non- infringement, opposition, interference, re- examination, post- grant review, inter partes review, nullification, or derivation actions in court or before patent offices, or similar proceedings challenging the validity, inventorship, ownership, enforceability, or scope of such patents, which may result in the patent claims being narrowed, invalidated, or held unenforceable or circumvented. Additionally, some countries, including China and India, have compulsory licensing laws under which we may be compelled to grant licenses to others. We may incur significant expenses in protecting our intellectual property and defending or assessing claims with respect to intellectual property owned by others. Any patent or other infringement litigation by or against us could cause us to incur significant expenses and divert the attention of our management. Even for our issued patents, we do not have a guarantee of patent term restoration and marketing exclusivity of the ingredients for our drugs under the Hatch- Waxman Amendments, even if we are granted FDA approval of our products. Furthermore, others may file patent applications or obtain patents on similar technologies or compounds that compete with our products. We cannot predict how broad the claims in any such patents or applications will be, and whether they will be allowed. Once claims have been issued, we cannot predict how they will be construed or enforced. We may infringe intellectual property rights of others without being aware of it. If another party claims we are infringing their technology, we could have to defend an expensive and time consuming lawsuit, pay a large sum if we are found to be infringing, or be prohibited from selling or licensing our products unless we obtain a license or redesign our product, which may not be possible. We also rely on trade secrets and proprietary know- how to develop and maintain our competitive position. We cannot be sure our measures to protect our trade secrets will be sufficient. Some of our current or former employees, consultants, scientific advisors, current or prospective corporate collaborators, may unintentionally or willfully disclose our confidential information to competitors or use our proprietary technology for their own benefit. Furthermore, enforcing a claim alleging the infringement of our trade secrets would be expensive and difficult to prove, making the outcome uncertain. Our competitors may also independently develop similar knowledge, methods, and know- how or gain access to our proprietary information through some other means. We may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights, as well as costs associated with lawsuits. If any other person files patent applications, or is issued patents, claiming technology also claimed by us in pending applications, we may be required to participate in interference proceedings in the U. S. Patent and Trademark Office to determine priority of invention. We, or our licensors, may also need to participate in interference proceedings involving our issued patents and pending applications of another entity. The European Patent Office and some national patent authorities have formal patent opposition processes where the validity of issued patents may be challenged. If a

patent opposition is filed, we, or our licensors, may also need to participate in opposition proceedings involving our issued patentsThe intellectual property environment in the oncolytic viruses field is particularly complex, constantly evolving and highly fragmented. We have not conducted freedom- to- use patent searches on all aspects of our product candidates or potential product candidates, and we may be unaware of relevant patents and patent applications of third parties. In addition, the freedom-to- use patent searches that have been conducted may not have identified all relevant issued patents or pending patents. We cannot provide assurance that our proposed products in this area will not ultimately be held to infringe one or more valid claims owned by third parties which may exist or come to exist in the future or that in such case we will be able to obtain a license from such parties on acceptable terms. We cannot guarantee that the practice of our technologies will not conflict with the rights of others. In some foreign jurisdictions, we could become involved in opposition proceedings, either by opposing the validity of another' s foreign patent or by persons opposing the validity of our foreign patents. ~~55We~~ **61We** may also face frivolous litigation or lawsuits from various competitors or from litigious securities attorneys. The cost to us of any litigation or other proceeding relating to these areas, even if deemed frivolous or resolved in our favor, could be substantial and could distract management from our business. Uncertainties resulting from initiation and continuation of any litigation could have a material adverse effect on our ability to continue our operations. If we infringe the rights of others, we could be prevented from selling products or forced to pay damages. If our products, methods, processes, and other technologies are found to infringe the proprietary rights of other parties, we could be required to pay damages, or we may be required to cease using the technology or to license rights from the prevailing party. Any prevailing party may be unwilling to offer us a license on commercially acceptable terms. We enjoy restricted geographical protection with respect to certain patents. Patents are of national or regional effect. While we will try to protect our technologies, products and product candidates with intellectual property rights such as patents throughout the world in major markets, the process of obtaining patents is time- consuming, expensive, and sometimes unpredictable in other countries. We may not pursue or obtain patent protection in all markets. Filing, prosecuting, and defending patents on all of our research programs and product candidates in all countries throughout the world would be prohibitively expensive, and, therefore, the scope and strength of our intellectual property rights will vary from jurisdiction to jurisdiction. We may become subject to claims challenging inventorship or ownership of our patents and other intellectual property. We generally enter into confidentiality and intellectual property assignment agreements with our employees, consultants, and contractors. These agreements generally provide that inventions conceived by the party in the course of rendering services to us will be our exclusive property. However, those agreements may not be honored and may not effectively assign intellectual property rights to us. Moreover, there may be some circumstances where we are unable to negotiate for such ownership rights. Disputes regarding ownership or inventorship of intellectual property can also arise in other contexts, such as collaborations and sponsored research. If we are subject to a dispute challenging our rights in or to patents or other intellectual property, such a dispute could be expensive and time consuming. If we were unsuccessful, we could lose valuable rights in intellectual property that we regard as our own. RISKS RELATING TO OUR SECURITIESWe cannot assure you that our common stock will be liquid or that it will remain listed on the NYSE American. Our ~~common~~ **Common** ~~stock~~ **Stock** is listed on the NYSE American. The NYSE American' s listing standards generally mandate that we meet certain requirements relating to stockholders' equity, stock price, market capitalization, aggregate market value of publicly held shares and distribution ~~requirements~~ **requirementsWe** ~~. We~~ cannot assure you that we will be able to maintain the continued listing standards of the NYSE American. The NYSE American requires companies to meet certain continued listing criteria including a minimum stockholders' equity of $ 6. 0 million if an issuer has sustained losses from continuing operations and / or net losses in its five most recent years, as outlined in the NYSE American Company Guide **and trading of the stock above $ 0. 10 per share** . The NYSE American Company Guide also states that the NYSE normally will not consider removing from listing securities of an issuer if it is in compliance with all of the following: a total value of market capitalization of at least $ 50. 0 million; 1, 100, 000 publicly- held shares; a market value of publicly held shares of at least $ 15. 0 million; and 400 round lot shareholders. ~~If our common stock falls below $ 0. 20 per share on a 30-~~ **In addition, the NYSE American has informed us that it can commence delisting proceedings and immediately suspend** trading **in** ~~- day average it will become subject to~~ the ~~continued~~ **event that our Common Stock trades at levels viewed to be abnormally low and no longer suitable for** listing **pursuant to** ~~evaluation and follow- up procedures set forth in~~ Section ~~1009~~ **1003 (f) (v)** of the NYSE American Company Guide **. Generally the NYSE American views trading at or below a price of $ 0. 10 to be abnormally low. New reverse stock split rules implemented by the NYSE American in January 2025 limit the circumstances under** which ~~could~~ **reverse stock splits can be used in order to cure low trading price deficiencies** , ~~among~~ **including** ~~other --~~ **the** ~~things, result in initiation of~~ immediate **suspension and** delisting ~~procedures~~ **of any company that has effected one or more reverse stock splits over the prior two year period with a cumulative ratio of 200 shares or more to one** . ~~In~~ **Based on these rules, due to the reverse stock split effected in August 2024, we would be limited in effecting a reverse stock split to cure a low price deficiency. 62As stated above, in** the event that we were to fail to meet the requirements of NYSE American per share price requirement **the NYSE American could commence delisting proceedings and immediately suspend trading of** ~~or~~ **our Common Stock o the NYSE American or if we fail to meet other requirements such as the** stockholders' equity requirement and we could not timely cure such deficiency, our listing could become subject to NYSE American continued listing evaluation and follow- up procedures, which could result in delisting procedures. We previously received notification from the NYSE American citing failure to comply with the minimum stockholders' equity continued listing standard as set forth in Part 10, Section 1003 of the Company Guide. Although in the past we have been able to cure previously cited deficiencies, there can be no assurance that we will continue to meet the NYSE American continued listing requirements. ~~56In~~ **In** addition, in the future we may not be able to **ensure that our Common Stock trades at levels not viewed to be abnormally low and no longer suitable for listing or** maintain minimum stockholders' equity and / or issue additional equity securities in exchange for cash or other assets, if available, to maintain certain minimum stockholders' equity required by the NYSE American. If we are delisted from the NYSE

American then our ~~common~~ **Common** ~~stock~~ **Stock** will trade, if at all, only on the over- the- counter market, such as the OTC Bulletin Board securities market, and then only if one or more registered broker- dealer market makers comply with quotation requirements. In addition, delisting of our ~~common~~ **Common** ~~stock~~ **Stock** could depress our stock price, substantially limit liquidity of our ~~common~~ **Common** ~~stock~~ **Stock** and materially adversely affect our ability to raise capital on terms acceptable to us, or at all. Delisting from the NYSE American could also have other negative results, including the potential loss of confidence by suppliers and employees, the loss of institutional investor interest and fewer business development opportunities. We cannot assure you that our ~~common~~ **Common** ~~stock~~ **Stock** will be liquid or that it will remain listed on the NYSE American. A failure to regain compliance with the NYSE American stockholders' equity requirements or failure to continue to meet the other listing requirements could result in a de- listing of our ~~common~~ **Common** ~~stock~~ **Stock** . The market price of our common stock has been and may continue to be volatile and adversely affected by various factors. Our stock price has fluctuated in the past, has recently been volatile and may be volatile in the future. By way of example, on ~~February 14~~ **March 19** , ~~2023~~ **2024** , the price of our common stock closed at $ ~~1~~ **11** . ~~13~~ **00** per share while on ~~November 14~~ **March 20** , ~~2023~~ **2024** , our stock price closed at $ ~~0~~ **15** . ~~39~~ **50** per share with no discernable announcements or developments by the company or third parties. We may incur rapid and substantial decreases in our stock price in the foreseeable future that are unrelated to our operating performance or prospects ~~. In addition, the outbreak of the novel strain of coronavirus (COVID- 19) has caused broad stock market and industry fluctuations~~ . The stock market in general and the market for biotechnology and pharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may experience losses on their investment in our common stock. The market price of our common stock could fluctuate significantly in response to various factors and events, including: ● investor reaction to our business strategy; ● the success of competitive products or technologies; ● our continued compliance with the listing standards of the NYSE American; ● regulatory or legal developments in the United States and other countries, especially changes in laws or regulations applicable to our products; ● results of our clinical trials; ● actions taken by regulatory agencies with respect to our products, clinical studies, manufacturing process or sales and marketing terms; ● variations in our financial results or those of companies that are perceived to be similar to us; ● the success of our efforts to acquire or in- license additional products or product candidates; ● developments concerning our collaborations or partners; ● developments or disputes concerning patents or other proprietary rights, litigation matters and our ability to obtain patent protection for our products; **63** ● our ability or inability to raise additional capital and the terms on which we raise it; ● declines in the market prices of stocks generally; ● trading volume of our common stock; ● sales of our common stock by us or our stockholders; ● general economic, industry and market conditions; ~~and~~57 -- **and** ● other events or factors, including those resulting from such events, or the prospect of such events, including war, terrorism and other international conflicts, ~~such as the recent Russian invasion of Ukraine as well as continued and new sanctions against Russia,~~ which restrict a wide range of trade and financial dealings ~~with Russia and Russian persons~~ , public health issues including health epidemics or pandemics, such as the outbreak of the novel coronavirus (COVID- 19), and natural disasters such as fire, hurricanes, earthquakes, tornados or other adverse weather and climate conditions, whether occurring in the United States or elsewhere, could disrupt our operations, disrupt the operations of our suppliers or result in political or economic instability. These broad market and industry factors may seriously harm the market price of our common stock, regardless of our operating performance. Further, recent increases are significantly inconsistent with any improvements in actual or expected operating performance, financial condition or other indicators of value. Since the stock price of our common stock has fluctuated in the past, has been recently volatile and may be volatile in the future, investors in our common stock could incur substantial losses. In the past, following periods of volatility in the market, securities class- action litigation has often been instituted against companies. Such litigation, if instituted against us, could result in substantial costs and diversion of management' s attention and resources, which could materially and adversely affect our business, financial condition, results of operations and growth prospects. There can be no guarantee that our stock price will remain at current prices or that future sales of our common stock will not be at prices lower than those sold to investors. Additionally, recently, securities of certain companies have experienced significant and extreme volatility in stock price due to short sellers of shares of common stock, known as a " short squeeze. " These short squeezes have caused extreme volatility in those companies and in the market and have led the price per share of those companies to trade at a significantly inflated rate that is disconnected from the underlying value of the company. Many investors who have purchased shares in those companies at an inflated rate face the risk of losing a significant portion of their original investment as the price per share has declined steadily as interest in those stocks have abated. While we have no reason to believe our shares would be the target of a short squeeze, there can be no assurance that we won' t be in the future, and you may lose a significant portion or all of your investment if you purchase our shares at a rate that is significantly disconnected from our underlying value. Our articles of incorporation and bylaws and Nevada law may have anti- takeover effects that could discourage, delay or prevent a change in control, which may cause our stock price to decline. Our articles of incorporation, as amended, our second amended and restated bylaws and Nevada law could make it more difficult for a third party to acquire us, even if closing such a transaction would be beneficial to our stockholders. The Board of Directors could authorize the issuance of an additional series of preferred stock that would grant holders preferred rights to our assets upon liquidation, special voting rights, the right to receive dividends before dividends would be declared to common stockholders, and the right to the redemption of such shares, possibly together with a premium, prior to the redemption of the common stock. To the extent that we do issue additional preferred stock, the rights of holders of common stock could be impaired thereby, including without limitation, with respect to liquidation. Provisions of our articles of incorporation, as amended, and our second amended and restated bylaws may also prevent or frustrate attempts by our stockholders to replace or remove our management. In particular, our articles of incorporation, as amended, and second amended and restated bylaws, among other things: ● provide the board of directors with the ability to alter the bylaws without stockholder approval; and ● provide that vacancies on the board of directors may be filled by a majority of directors in office,

although less than a quorum. **64** ~~We do not intend to pay dividends in the foreseeable future on our common stock. We have never paid cash dividends on our common stock. We currently intend to retain our future earnings, if any, to finance the operation and growth of our business and currently do not plan to pay any cash dividends in the foreseeable future. If we do not pay dividends, our common stock may be less valuable because a return on your investment will only occur if the market price of our common stock price appreciates. 58~~