Risk Factors Comparison 2024-03-01 to 2023-03-14 Form: 10-K

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

Risks Related to Our Financial Position and Need for Additional Capital **● Our recurring losses from operations raise substantial doubt that we will be able to continue as a going concern and our independent registered public accounting firm has issued an audit report that includes an explanatory paragraph referring to the uncertainty regarding our ability to continue as a going concern without additional capital becoming available.** ● We have incurred losses since inception and anticipate that we will continue to incur losses for the foreseeable future. ● We will require additional capital to fund our operations. ● Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates. ● We have a limited operating history and no history of commercializing pharmaceutical products. Risks Related to Development, Clinical Testing, Manufacturing and Regulatory Approval ● We are heavily dependent on the success of **our product candidates,** IMC- 1 ~~, our lead candidate~~ **and IMC- 2** , which ~~is~~ **are** still under clinical development, and if ~~this~~ **these product** ~~candidate~~ **candidates** ~~does~~ **do** not receive regulatory approval or, if approved, our commercialization efforts are unsuccessful, our business may be harmed. ● We may face future business disruption and related risks from the spread of infectious disease, including coronavirus 2019 variants, which could have a material adverse effect on our business. ● Clinical trials are expensive, time- consuming and difficult to design and implement, and involve an uncertain outcome. ● If we are ultimately unable to obtain regulatory approval for any of our product candidates, our business will be substantially harmed. ● Results of preclinical studies, early clinical trials or analyses may not be indicative of results obtained in later trials. ● The market opportunities for ~~IMC- 1~~ **our product candidates** , if approved, may be smaller than we anticipate. ● We may never obtain approval for or commercialize IMC- 1 **, IMC- 2** or any other ~~development~~ **product** candidate in any other jurisdiction, which would limit our ability to realize their full global market potential. Risks Related to Commercialization ● We face significant competition from other biotechnology and pharmaceutical companies and our operating results will suffer if we fail to compete effectively. ● Even if IMC- 1 **, IMC- 2** or any other **product** candidate we develop receives marketing approval, it may fail to achieve market acceptance by physicians, patients, third- party payors or others in the medical community necessary for commercial success. ● If we are unable to establish sales, marketing and distribution capabilities either on our own or in collaboration with third parties, we may not be successful in commercializing IMC- 1 **or IMC- 2** , if approved. Risks Related to Our Dependence on Third Parties ● We currently rely on third- party contract manufacturing organizations, or CMOs, for the production of clinical supply of IMC- 1 and **IMC- 2 and** intend to rely on CMOs for the production of commercial supply of IMC- 1 **and IMC- 2** , if approved. ● We intend to rely on third parties to conduct, supervise and monitor our clinical trials. Risks Related to Healthcare Laws and Other Legal Compliance Matters ● Enacted and future healthcare legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our ~~development~~ **product** candidates. ● We are subject to environmental, health and safety laws and regulations, and we may become exposed to liability and substantial expenses in connection with environmental compliance or remediation activities. ● If we become profitable, our ability to use our net operating loss carryforwards and other tax attributes to offset future taxable income or taxes may be subject to limitations. Risks Related to Our Intellectual Property ● Our patents may be challenged in courts or in patent offices. ● Changes in patent laws or patent jurisprudence could diminish the value of patents in general. ● We enjoy only limited geographical protection with respect to certain patents. ● We may need to license certain intellectual property from third parties, and such licenses may not be available or may not be available on commercially reasonable terms. Risks Related to Our Employees, Managing Our Growth and Our Operations ● Our future success depends on our ability to retain our key personnel and to attract, retain and motivate qualified personnel. ● We expect to expand our development, regulatory, and sales and marketing capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations. ● We may engage in acquisitions that could disrupt our business, cause dilution to our stockholders or reduce our financial resources. Risks Related to Our Common Stock ● If we are unable to maintain listing of our common stock on the Nasdaq Capital Market or another national stock exchange, it may be more difficult for our stockholders to sell their shares of common stock. ● The market price of our common stock is highly volatile. ● We do not intend to pay dividends on our common stock so any returns will be limited to the value of our stock ~~. ● Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval~~ . 5 PART IItem 1. BusinessOur CompanyWe were incorporated under the laws of the State of Delaware on December 16, 2020 through a corporate conversion just prior to the Company' s initial public offering (" IPO "). The Company was originally formed on February 28, 2012 as a limited liability company under the laws of the State of Alabama as Innovative Med Concepts, LLC. On July 23, 2020, the Company changed its name from Innovative Med Concepts, LLC to Virios Therapeutics, LLC. We are a development- stage biotechnology company focused on advancing novel antiviral therapies to treat diseases associated with a viral triggered abnormal immune response such as fibromyalgia (" FM ") **and Long- COVID (" LC ")** . Overactive immune response related to activation of tissue resident **herpesvirus** ~~herpes virus~~ has been postulated to be a potential root cause of chronic illnesses such as FM, irritable bowel disease (" IBS "), **LC,** chronic fatigue syndrome and other functional somatic syndromes, all of which are characterized by a waxing and waning manifestation of disease **, often triggered by events which compromise the immune system** . While not completely understood, there is general agreement in the medical community that activation of the **herpesvirus** ~~herpes virus~~ is triggered by some form of environmental and / or health stressor. Our lead **product** ~~candidate~~ **candidates** , IMC- 1 **and IMC- 2** , **are** ~~is a~~ novel, proprietary, fixed dose ~~combination~~ **combinations** of ~~famciclovir~~ **anti- herpes antivirals** and celecoxib. IMC- 1 ~~represents~~ **is** a

novel combination **of famciclovir and celecoxib intended** ~~, dual- mechanism antiviral therapy designed~~ to synergistically suppress **herpesvirus** ~~herpes virus~~ activation and replication, with the end goal of reducing viral mediated disease burden. IMC- **2 is a combination of valacyclovir and celecoxib that, like IMC-** 1 **, is intended to synergistically suppress herpesvirus activation and replication with a more specific activity against the Epstein- Barr virus (herpesvirus HHV- 4). IMC- 1 and IMC- 2** ~~combines~~ **combine** two specific mechanisms of action purposely designed to inhibit **herpesvirus** ~~herpes virus~~ activation and replication, thereby keeping the **herpesvirus** ~~herpes virus~~ in a latent (dormant) state or " down- regulating " the ~~virus~~ **herpesvirus** from a lytic (active) state back to latency. The famciclovir component of IMC- 1 **and the valacyclovir component of IMC- 2** ~~inhibits~~ **inhibit** viral DNA replication. The celecoxib component of IMC- 1 **and IMC- 2** inhibits cyclooxegenase- 2 (~~"~~ COX- 2 ~~"~~) and to a lesser degree **cyclooxegenase- 1 (** COX- 1 **)** enzymes, **which are** used by the **herpesvirus** ~~herpes virus~~ to amplify or accelerate its own replication. We are unaware of any other antivirals **currently** in development for the treatment of FM **or related conditions** . We believe this novel approach was a germane consideration in the U. S. Food and Drug Administration (" FDA ") designating IMC- 1 for fast- track review status for the treatment of FM. ~~Furthermore,~~ IMC- 1 has **also** been granted a synergy patent based on the fact that neither **of** ~~antivirals nor NSAIDS / COX- 2 inhibitors (~~ the individual components ~~of IMC- 1)~~ has proven effective in the management of FM ~~when used as a monotherapy~~ , yet the ~~dual- mechanism~~ combination therapy generated a result ~~in preliminary studies~~ that **is** ~~appears to be~~ greater than the sum of its parts. **Our novel combination antiviral approach (combining viral DNA polymerase inhibitor COX- 2 inhibitor) delivers clinical benefits for patients suffering from diseases with a suspected viral mediated catalyst, including FM and LC. We have received FDA feedback on our proposal to advance IMC- 1 into Phase 3 development for the treatment of FM. A recently completed open- label, exploratory trial demonstrated that patients treated with IMC- 2 exhibited clinically and statistically significant improvement of their LC symptoms of fatigue, orthostatic intolerance, anxiety and pain. These encouraging results lead to the Company funding a new, phase 2 investigator- initiated study assessing two dosage strengths of IMC- 2 versus placebo. The results of this study are expected to be released in mid- 2024. We have received FDA feedback on our proposed Phase 2b study of IMC- 2 for the treatment of LC and project to commence this trial in the second half of 2024, either as a stand- alone entity or via partnership. 6** Dormant **Herpesvirus** ~~Herpes Virus~~ is Reactivated by External Triggers and AmplifiesIts Own Replication via Cyclooxygenase (COX **-** 1 and COX **-** 2) **EnzymesFibromyalgia Program BackgroundThe** ~~Enzymes6 IMC- 1' s Novel, Synergistic Antiviral Mechanism Suppresses Viral Replication, Demonstrates FM Treatment EffectThe~~ potential of IMC- 1 in FM was demonstrated by statistically significant improvement versus placebo in the primary endpoint of pain reduction in our double- blinded, placebo- controlled, randomized Phase 2a proof- of- concept study in FM patients. This proof- of- concept study generated statistically significant clinical data on the effects of IMC- 1 on both primary pain assessment and secondary measures of pain reduction, reduction in fatigue and improvement in the global health status in patients diagnosed with FM. A result is considered to be statistically significant when the probability of the result occurring by random chance, rather than from the efficacy of the treatment, is sufficiently low. The conventional method for measuring the statistical significance of a result is known as the " p- value, " which represents the probability that random chance caused the result (e. g., a p- value = 0. 001 means that there is a 0. 1 % or less probability that the difference between the control group and the treatment group is purely due to random chance). Generally, a p- value less than 0. 05 is considered statistically significant and may be supportive of a finding of efficacy by regulatory authorities. However, regulatory authorities, including the FDA and EMA, do not rely on strict statistical significance thresholds as criteria for marketing approval and maintain the flexibility to evaluate the overall risks and benefits of a new treatment. **7** The table below demonstrates the significant differences observed in the proof- of- concept study between IMC- 1 and placebo in change from baseline using both the Numerical Rating Scale (NRS) 24- hour recall pain data and the Revised Fibromyalgia Impact Questionnaire (FIQ- R) with LOCF / BOCF imputation. ~~7~~ IMC- 1 also exhibited consistent improvement across several secondary FM treatment outcomes, including 50 % responder analysis, improved functional assessments, lower chronic fatigue, increased time to rescue medication and improvements in FM patient' s overall global health status. One key secondary measure assessing a 30 % pain reduction analysis was approaching but did not meet statistical significance (p = 0. 052). In the Phase 2a study, IMC- 1 demonstrated a lower discontinuation rate due to adverse events as compared with placebo. There were no deaths during the study and only three serious adverse events (" SAEs ") were reported. The two SAEs in the IMC- 1 group were a non- ST segment elevation myocardial infarction and a facial cellulitis and the one SAE in the placebo group was a right breast micro- metastatic ductal carcinoma. One of the 3 SAEs was considered possibly related to study treatment — the non- ST segment elevation myocardial infarction that occurred early in the study in a 47- year- old patient treated with IMC- 1. The causal relationship of this SAE to treatment with IMC- 1 cannot be ruled out and as such was determined to be " possibly related " to IMC- 1; however, the patient' s underlying coronary artery disease and strong family history of premature cardiac disease suggest that other causal factors might also have been involved. Based on the significant unmet need in treating FM and the aforementioned Phase 2a FM data, IMC- 1 has been granted FDA designation for fast- track review status. In addition, the novel mechanism of IMC- 1 has enabled us to secure composition of matter intellectual property (patent) protection to 2033. Following on from our successful Phase 2a study, we held an end of Phase 2 meeting with the FDA. In the meeting, we agreed to initiate either a Phase 2b study or a Phase 3 program after we provide animal toxicology study data, to conduct a human PK study and a clinical trial protocol that includes monitoring renal function through standard safety labs to the FDA. A human PK study with the combined tablet of IMC- 1 was completed and performed as expected, with no drug- drug interactions and no adverse events. Multiple dose PK of IMC- 1 was well characterized and provides additional data to better understand the PK profile of IMC- 1. As a result, we have progressed development of IMC- 1 from Phase 2a proof- of- concept to a larger scale Phase 2b study, known as FORTRESS, (Fibromyalgia Outcome Research Trial Evaluating Synergistic Suppression of HSV- 1), for the treatment of FM. The Phase 2b and chronic toxicology studies are planned components of the registration package supporting Phase 3 requirements. In September 2022, we announced the top line results from our

FORTRESS study in FM. Overall, the FORTRESS study did not achieve statistical significance on the prespecified primary efficacy endpoint of **8** change from baseline to Week 14 in the weekly average of daily self- reported average pain severity scores comparing IMC- 1 to placebo (p = 0. 302). However, analysis of the data showed a bifurcation of response based on the timing of patient enrollment in the FORTRESS study. During the first half of the trial from June 2021 to November 2021, for the patients who were enrolled (n = 208) (Cohort 1) when the Delta variant of COVID- 19 was the dominant strain in the U. S., full vaccination rates were below 50 % and some form of quarantining **had been in place for over a year and** was still in place in most geographies, IMC- 1 demonstrated no improvement versus placebo- treated patients. Conversely, during the second half of the trial from November 2021 to April 2022, for the patients who were enrolled (n = 214) (Cohort 2) when vaccination rates improved, the Omicron variant of COVID- 19 became the dominant U. S. strain and quarantining restrictions were ~~less~~ **lessened** , IMC- 1- treated patients demonstrated a statistically significant improvement on the primary pain reduction endpoint (p = 0. 03) at Week 14, as well as a statistically significant improvement in the key secondary PROMIS Fatigue assessment (p = 0. 006) and the Fibromyalgia Impact Questionnaire- Revised (FIQR) symptoms domain score (p = 0. 015). ~~See the figure below.~~ We believe the likelihood of such a differential response based on the timing of patient enrollment is highly unlikely due to chance or a random occurrence, thus further analysis of the data was warranted, particularly in the context of our previous IMC- 1 Phase 2a study success. ~~8~~ Importantly, IMC- 1 displayed a first in class safety profile with excellent tolerability and with only 4. 6 % of IMC- 1 treated patients dropping out due to adverse events, as compared with 8. 1 % of placebo treated patients. No adverse event category in the IMC- 1 group exceeded a 4 % rate with the exception of COVID- 19 infection. Overall discontinuations were 18. 5 % in the IMC- 1 treated group versus 23 % in the placebo treated group. Patients in the FORTRESS trial were randomized one- to- one to either IMC- 1 or placebo and patient background demographics and baseline pain scores were well matched. In addition to potential COVID pandemic related impacts, a number of factors differed between those patients recruited during the first half versus the second half of the FORTRESS study. For example, 70 % of the patients enrolled in the first half of the study were " Prior " patients who had previous relationships with their respective FORTRESS research sites and / or were participants in prior FM clinical trials. In contrast, over 50 % of the FORTRESS subjects enrolled later in the study were " New ", community based patients who had not participated in prior FM clinical trials. These New patients were generally recruited through social media advertising. Based on this demographic understanding, the team assessed how New patients versus Prior treated patients responded to IMC- 1 treatment, in both cases versus placebo. Encouragingly, New patients demonstrated statistically significant improvement on the primary endpoint of reduction in FM related pain versus placebo, irrespective of when they enrolled in the study. In addition, New patients demonstrated statistical improvement in key secondary measures, including reduction in fatigue, improvement on the FIQR total scores and reductions in depression, the latter of which is believed to be important given depression is associated with the increased rate of suicide amongst FM patients. Conversely, Prior patients did not show improvement in FM related pain when compared with placebo. In addition to the difference in response between Prior and New patients, we also observed differences within these groups based on timing of recruitment. We believe that recruitment early in the FORTRESS study was much more strongly impacted by pandemic related issues, as opposed to those recruited in 2022. Factors such as staffing levels, training, rates of absenteeism, and supply related issues all improved at the site level as we moved into 2022. ~~The figure below shows the statistically significant primary endpoint result when analyzing the New patient population. 9~~ Based on the analysis of the FORTRESS data, we believe focusing the forward development of IMC- 1 on New FM patients represents a viable and manageable path forward. The Company ~~is scheduled to meet~~ **met** with the FDA in March 2023 to discuss the most appropriate next steps in advancing IMC- 1 development as a treatment for FM. **The** ~~If alignment can be reached, management will consider raising additional capital to fund future research and / or seek a partner to develop or co- develop IMC- 1 as a treatment for FM. For the~~ Phase 3 program **agreed with FDA includes** ~~, we intend to run~~ two qualifying pivotal trials demonstrating the safety and efficacy of IMC- 1 treating patients with FM. **One of the Phase 3 studies will be a four- arm, multifactorial design to demonstrate the relative safety and efficacy of IMC- 1 as compared to celecoxib alone, famciclovir alone and placebo.** The ~~first~~ **other** Phase 3 study is planned ~~to be a four- arm, multifactorial design to demonstrate the relative safety and efficacy of IMC- 1~~ as ~~compared to celecoxib alone, famciclovir alone and placebo. The second Phase 3 study is planned to be~~ a two- arm study comparing IMC- 1 to placebo. All patients from the **two pivotal** Phase 3 ~~program~~ **studies** will be offered the opportunity to enroll into an open label safety ~~follow- on~~ extension study in which all patients will be treated with IMC- 1 ~~,~~**. Long- term safety data is required for chronic therapy approval. We are presently exploring partnership opportunities as the primary means by** which **to advance IMC- 1 into** ~~is the third key component of the~~ Phase 3 **development** ~~program proposal~~ . **9** Background of Fibromyalgia (FM) FM is a widespread chronic pain disorder including severe symptoms of fatigue lasting 3 months or longer in duration. FM is also characterized by generalized aching, muscle stiffness, non- restorative sleep, chronic fatigue, depression, cognitive impairment and disturbances in bowel function. Researchers estimate that FM affects 2 % to 8 % of the US population and is the second most common " rheumatic disorder, " second to osteoarthritis. The National Fibromyalgia & Chronic Pain Association estimates that 10 million Americans have FM. We estimate that there are approximately 3. 6 million patients in the U. S. that have been diagnosed with FM, with approximately 2 million **patients** being treated. Because there are no specific clinical or laboratory tests available to diagnose FM, diagnosis is established by demonstrating that a patient has widespread chronic pain in 7 or more of the 19 bodily locations for at least 3 months in duration. Additionally, these patients may ~~10~~ also have non- restorative sleep, life altering fatigue, and cognitive impairment. The underlying cause of FM has remained elusive and frustrated treating physicians and the scientific community alike. To date, the three products approved by the FDA for the treatment of FM have the potential to cause troublesome side effects and / or deliver limited efficacy ~~. The American College of Rheumatology (" ACR ") has provided working definitions for the diagnosis of FM. ACR published its 1990 criteria and 2010 criteria to assist physicians in making this diagnosis. The 1990 criteria require that patients have widespread chronic pain in all four quadrants of the body for at least 3 months duration and at least 11 out of 18 predefined tender point sites are painful. The~~

2010 criteria revision introduced the concepts of a widespread pain index (" WPI ") and symptom severity scale score (" SSS ") for at least 3 months and no other explanation for the chronic symptoms. In 2016, the ACR developed a revision of the 2010 / 2011 FM criteria. FM may now be diagnosed in adults when all of the following criteria are met: ● WPI ≥ 7 and SSS score ≥ 5 OR WPI = 4- 6 and SSS score ≥ 9; ● Generalized pain, defined as pain in at least 4 of 5 regions, is present; and ● Symptoms have been present at a similar level for at least 3 months. A diagnosis of FM is valid irrespective of other diagnoses and does not exclude the presence of other clinically important illnesses . Fibromyalgia: A Serious Condition with Unmet Medical NeedFM is associated with increased mortality due to suicide or accident. Researchers evaluating over 8, 186 patients with FM across three different sites in the United States between 1974 and 2009 found that individuals with FM were more than three times as likely (odds ratio (" OR ") = 3. 31) to die from suicide compared to the general population and were at increased risk of death due to accidents (OR = 1. 45, 95 % confidence interval (" CI "); 1. 02- 2. 06). This led the authors to speculate that some of the deaths that were classified as accidents may actually have been suicides, suggesting an even higher rate of suicide among these patients. This increased risk of mortality associated with the diagnosis of FM suggests that FM is a serious disease and that treatment of FM represents a significant unmet medical need. In 2018, the FDA conducted a Patient- Focused Drug Development (" PFDD ") meeting with over 400 individuals or caregivers of individuals who experience chronic pain. Based on input from that meeting, the FDA reported that despite patient use of FDA approved and off- label therapies, the majority of FM patients continue to experience worsening pain, fatigue, cognitive impairment and other symptoms over time that requires increasing utilization of significant healthcare resources. In a 2001 study of 100 cases of FM in Ontario, Canada, patients reported spending most of at least one day in bed over the previous two weeks because of their health, and they spent more total days in bed compared to pain control and general control groups. Such unresolved morbidity significantly impacts the day- to- day functioning of patients suffering from FM. Under the fifth authorization of the Prescription Drug User Fee Act, from 2013- 2018, the FDA conducted 24 disease specific PFDD meetings to better understand patients' perspectives on their condition and the available therapies to treat their conditions. On March 26, 2014, the FDA held a public meeting with patients suffering from FM. The meeting was chaired by 5 panelists from the FDA who interviewed 10 patients with FM who expressed FM to be a condition with an unmet medical need. Patients described the impact of FM on their daily lives, and their experiences with currently available therapies. During FDA' s meeting on the diagnosis, symptoms and treatment options for FM, the FDA acknowledged that: " There is a continuing need for treatments to better manage symptoms and treat the underlying condition. " Patients described prescription drugs as having widely varying degrees of effectiveness, with many participants noting limited benefits or decreased benefit over time. Additionally, even when treatment was effective, many FM patients described 11 that they could not adhere to treatment regimens because they were unable to tolerate treatment side effects including, but not limited to, cognitive issues, mood disruptions, nausea, high blood pressure, and, in certain cases, severe withdrawal symptoms. The following complaints, summarized from patient comments from the PFDD meeting and public comments submitted to the meeting docket, demonstrate the significant limitations of the three drugs approved by FDA for the management of FM. Lyrica (pregabalin) — FDA Approved June 2007a. Discontinuation of Lyrica after a few weeks due to negative side effects, most notably drowsiness, cognitive issues, dizziness, effects on mood, and weight gain. Other side effects noted included depression and swelling of the mouth and tongue. b. Loss of effectiveness over time. c. Withdrawal symptoms after discontinuing Lyrica. Cymbalta (duloxetine) — FDA Approved June 2008 (1) Negative side effects such as headache, vertigo, sleep issues, fatigue, mood disruptions, loss of libido, nausea, cognitive issues, weight gain, swelling of the mouth and tongue, vision problems and suicidal thoughts. (2) Severe withdrawal symptoms after discontinuing Cymbalta. Savella (milnacipran) — FDA Approved January 2009a. Discontinuation of Savella due to side effects, such as nausea, vomiting, high blood pressure, excessive sweating, and mood disruptions. b. Ineffective or intolerable side effects. Each of the three drugs approved by the FDA for the management of FM, Lyrica, Cymbalta and Savella, modify central pain processing; pregabalin via modulation of voltage- gated calcium channels, and duloxetine and milnacipran via serotonin and norepinephrine reuptake inhibition (" SNRI "). Current treatments, including FDA approved therapies, prescription drugs used off- label and other non- prescription treatments are generally ineffective in managing FM for most patients. The table below shows the percentage use of different therapies for FM based on data from a 2012 study lead by Dr. Rebecca Robinson, a FM researcher, and her colleagues. The study evaluated the burden of illness and treatment patterns for patients with FM from July 2008 through May 2010 in 58 care settings in the United States, including Puerto Rico. A majority of the 91 physicians participating were either rheumatologists or primary care physicians. There were 1, 700 patients with FM who were mostly female and white with a mean age of 50. 4 years and duration of illness of 5. 6 years. The study shows the burden of illness is high, patients were taking on average 2. 6 medications concurrently to treat their FM and the treatments with the most evidence to support their use were not always the treatments most frequently chosen. Opioids were one of the most commonly used treatments, even though there is no evidence opioids are effective in treating FM 12 related pain. The FDA issued a statement in February 2019 indicating the agency will be pushing for increased research and development of non- addictive, non- opioid chronic pain treatments. The chart below comes from an observational study in 2013 led by Dr. Rebecca Robinson. Researchers assessed the 12- month treatment patterns and outcomes for patients starting a new medication for FM in actual clinical practice. Data from 1, 700 patients was collected at baseline and 1, 3, 6, and 12 months using a regression model. Patients were started on 145 unique drugs and over 75 % took two or more medications concurrently for FM at each time point assessed. The most common reason for discontinuation was adverse events (63. 4 %) followed by lack of efficacy (30. 3 %). This study shows that adverse events can have a detrimental impact on adhering to medications used chronically to treat FM. The polypharmacy (both indicated and off- label medications) utilized by patients to manage their FM symptoms, along with a demonstrated lack of adherence to currently approved FDA treatments, reflect side 13 effects and / or lack of efficacy of currently available drugs and treatments. It also indicates a very significant unmet medical need, with associated cost burden to payers and loss of productivity of patients. With the exception of IMC- 1, we are not aware of any drugs currently in development and directed at the management of FM that deploy an antiviral

~~mechanism (s) of action. Current products are used to ameliorate FM symptoms rather than address an underlying cause (s) of the disease. In contrast, the mechanism of action of IMC- 1 targets a potential underlying, root cause of FM- herpes virus reactivation. Clinical trials are conducted under widely varying conditions. As a result, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice. However, generally speaking, in clinical trials the discontinuation rate for the three central nervous system- mediated, FDA approved drugs, is approximately twice that of patients treated with placebo. This is important as inability to tolerate a medicine can lead to discontinuation of therapy.~~ Our Novel Mechanism of Action (" MOA ") Scientists and clinicians **generally** agree that patients with FM have a problem with central pain processing. The exact causality of the heightened pain sensitivity in FM is poorly understood. What is generally agreed is that the central sensitization seen in FM is secondary to a combination of genetic and environmental factors that render the patient susceptible to developing the widespread chronic pain and related symptoms seen in FM. We believe that, when FM patients are exposed to significant life stressors, be they physical or emotional, **there is** ~~it results in an~~ abnormal stress ~~or herpes virus mediated~~ **to the immune system allowing herpesviruses to reactivate. This reactivation event, in turn, leads to a herpesvirus associated** immune response. **Herpesviruses** ~~Herpes viruses~~ are unique in that they remain in a dormant state (latency) in ~~neuronal nuclei~~ **differing tissue types, depending on the strain,** as nonintegrated, circular DNA associated with nucleosomes, with recurrent reactivations for the life of the host. We believe it is likely that nerve resident viral herpetic reactivation is necessary for the nociceptive response seen in FM. This cyclical process of virus reactivation and lytic infection is postulated to perpetuate FM symptoms in these patients. Our novel therapeutic is directed at interrupting the ongoing immune response by suppressing the **herpesvirus** ~~herpes virus~~, which suppresses the abnormal stress response, thereby alleviating the central pain processing abnormality and other FM symptoms. Studies have shown that neither antivirals nor COX- 2 / NSAIDS taken alone result in a meaningful clinical benefit. However, when administered in combination, the synergistic response was unexpected and promising. This IMC- 1 synergistic response resulted from a combination of famciclovir inhibiting viral DNA polymerase and celecoxib inhibiting upregulation of COX- 2 (and to a lesser extent **,** COX- 1). There have been multiple published studies using NSAIDS / COX- 2' s in the treatment of FM. According to a 2017 review published in the Cochrane Database of Systemic Reviews, NSAIDs / COX- 2' s alone were shown to be no more effective than placebo in treating pain associated with FM. Products included in the review were ibuprofen 2400mg daily, naproxen 1000mg daily, tenoxicam 20mg daily and **10** COX- 2 etoricoxib 90mg daily. Antiviral monotherapy treatment of FM was studied by Dr. Sally A. Kendall and her colleagues and published in 2004 in the Journal of Rheumatology. Dr. Kendall evaluated valacyclovir 1 gram three times a day vs placebo in 60 patients with FM. The results showed no difference in change of pain between valacyclovir and placebo. Virally induced upregulation of COX enzymes is important for efficient viral replication. An article published by Dr. Lynn W. Enquist, a professor at Princeton University, and his colleagues in the Journal of Virology (2004), demonstrated that many **herpesviruses** ~~herpes viruses~~ significantly up- regulate COX- 2 and to a lesser degree COX- 1. In an article published by Yuehong Liu and colleagues in 2014 in The Scientific World Journal, they estimated 14- fold increase in COX- 2, 1. 8- fold increase in COX- 1 during **herpesvirus** ~~herpes virus~~ infection. Celecoxib inhibits COX- 2 and to a lesser degree COX- 1, both of which are critical to the replication and growth of live virions. In general, COX- 2 inhibition is regarded as more important than COX- 1 inhibition for the suppression of **herpesvirus** ~~herpes virus~~ reactivation. COX- 2 activation is involved in the induction of herpetic recurrences, and COX- 2 inhibition is accompanied not only by a reduction of viral shedding, but also a reduction of viral DNA in nerve ganglia. ~~14~~ The anti- **herpesvirus** ~~herpes virus~~ MOA of the nucleoside analogs (which include famciclovir) is well characterized, and this drug class has been used to treat viruses over decades. In its active state famciclovir is initially phosphorylated to a monophosphate form, after which it is converted to penciclovir triphosphate by cellular kinases within virus- infected cells. Penciclovir triphosphate, the active moiety, competitively inhibits viral DNA polymerase, reducing viral DNA synthesis and replication. The specificity of penciclovir for viral DNA polymerase is an important contributor to its benign safety profile. Famciclovir interrupts DNA polymerase and, in combination with celecoxib, results in synergistic viral suppression. If definitively demonstrated through pivotal clinical trials, the efficacy, safety and tolerability, along with the combined MOA, would, we believe, differentiate IMC- 1 from current standard of care and near- term pipeline drugs, while providing new opportunities in the treatment of other chronic pain conditions within the Somatic Symptom Disorders. Discovery and DevelopmentThe initial clinical evidence supporting the development of an antiviral plus COX- 2 / NSAID combination to address FM was first derived through clinical observation in patients with IBS. IBS patients treated with famciclovir, who were serendipitously also placed on celecoxib to treat their arthritis, showed significant improvement not only in their IBS, but also FM, fatigue, and headaches. In particular, FM patients conveyed that they felt noticeably better when placed on the combination of famciclovir and celecoxib. We believe that stress and other environmental factors reactivate a persistent (indolent) herpes infection, resulting in a continuous nociceptive stimulation and immune response. The cyclical process of virus reactivation and lytic infection of **herpesvirus** ~~herpes virus~~ perpetuates FM symptoms. To interrupt and reverse viral reactivation and immune response, and resultant continuous nociceptive stimulation requires the suppression of the **herpesvirus** ~~herpes virus~~, reverting it into a dormant (latency) status. We believe the coaction (synergy) of therapeutic agents with different antiviral properties is required to suppress **herpesvirus** ~~herpes virus~~ and reverse the symptoms of FM. Famciclovir, a nucleoside analog DNA inhibitor, inhibits the replication of viral DNA. The **herpesvirus** ~~herpes virus~~ upregulates COX- 2, and to a lesser degree COX- 1, and this upregulation of COX enzymes is critical for efficient viral replication. Celecoxib effectively blocks virally induced upregulation of COX enzymes, hence the combined activity of Famciclovir and Celecoxib results in the reversion of the **herpesvirus** ~~herpes virus~~ to latency. IMC- 1 interrupts the chronic dysfunctional immune response to the **herpesvirus** ~~herpes virus~~ infection by suppressing viral replication and re- emergence from latency. This results in the suppression of the abnormal stress response seen in IBS and FM, thereby alleviating the central pain processing abnormality. Multiple published clinical studies have confirmed that neither antivirals (such as famciclovir) nor

COX- 2 / NSAIDs (such as celecoxib) administered singly deliver any meaningful clinical benefit. Based on Phase 2a study results, the synergy of the fixed- dose combination of famciclovir and celecoxib (IMC- 1) has potential as a FM therapy. If approved, this could differentiate IMC- 1 from current standard of care and pipeline products and, we believe, **11** alter treatment outcomes in FM, and potentially a number of other chronic pain conditions in the Somatic Symptom Disorders where **herpesviruses** ~~herpes viruses~~ may play a role. ~~15~~ Biomarker — Gastrointestinal Tissue Study to see if Herpes Simplex Type 1 (" HSV- 1 ") is present in IBS / FMThe stomach of FM patients is one of the few sites that presents an opportunity for biopsy of tissue to determine if FM patients are burdened with **an** ~~herpes virus infection, where active~~ **actively replicating herpesvirus** ~~FM is resultant upon reactivation of herpes virus~~ infection. We have postulated that **herpesvirus** ~~herpes virus~~ infected nerve tissue located in the gastric mucosa provides a site for biopsy and represents an excellent site to confirm active **herpesvirus** ~~herpes virus~~ infection in patients with recurrent active FM. To test this hypothesis, we engaged the University of Alabama to analyze GI biopsy tissue to search for active HSV- 1 virus. Thirty patients with documented FM with chronic GI complaints had their stomach biopsied with samples sent to the University of Alabama for analysis by Carol Duffy PhD, University of Alabama virologist. Fifteen controls without chronic pain or FM and without chronic GI conditions were studied as the comparator arm to the open study. The GI biopsies were evaluated for HSV- 1 infection by Immunoblot analysis for viral non- structural protein (ICP8) with PCR used to detect herpesvirus DNA sequence. ICP8 is only found during an active HSV- 1 infection. A summary of this data is presented below. The study found that 83 % of patients with FM and chronic GI conditions had **detectable** ICP8, a protein only found in ~~active~~ **actively replicating** HSV- 1 infections ~~as demonstrated in the GI biopsy~~. While only 9 % of control patients had ICP8 (p = 0. 0001). The study also analyzed patients suffering from symptoms of IBS and demonstrates a strong correlation with HSV- 1 (p = 0. 0005) as well, when compared to controls. The correlation of HSV- 1 activation to FM (and IBS) was shown and we believe corroborates the underlying mechanistic rationale for IMC- 1. **12 Long- COVID (LC) Program BackgroundThe diagnosis of LC, as defined by the Center for Disease Control (" CDC "), is new, recurring or continuation of symptoms, most notably fatigue and post exertional malaise, greater than 4 weeks after an acute COVID- 19 infection. Research highlights that up to 30 % of LC patients were asymptomatic during their acute COVID- 19 illness. A 2022 CDC estimate revealed that 6. 9 % of adults had LC in 2022 and 3. 4 % of adults exhibited active LC sequelae at the time of the survey. As new research highlights, the majority of COVID- 19 morbidity is associated not with acute COVID- 19, but with LC, as evidenced by more than one in four LC adults reporting significant activity limitations. Presently, there are no approved treatments for LC illness.** The **only approved COVID- 19 treatment, Paxlovid, failed to improve LC sequelae. Just as in FM, we believe many of the symptoms associated with Post- Acute Sequelae of COVID- 19 infection (" PASC ") are related to secondary reactivation of tissue resident herpesviruses, and that a suppressive antiviral treatment regimen may be helpful in managing these patients. Recent studies indicate reactivated herpesvirus infection lead to LC, as opposed to residual SARS- CoV- 2 virus after the acute infection. Reactivated herpesviruses, such as Epstein- Barr virus (" EBV "), are associated with fatigue and cognitive dysfunction, the predominant symptoms of LC. According to Olson et al, nucleoside analogue antiviral agents are activated by EBV thymidine kinase (BXLF1) or serine / threonine protein kinase / phosphotransferase (BGLF4), which are expressed only during the lytic phase of EBV replication (Olson, 2013). Furthermore, Lin and colleagues concluded that nucleoside analogs, such as valacyclovir, have been developed with the goal of inhibiting the EBV lytic cycle by blocking DNA replication (Lin, 1986). A multitude of studies now suggest that some of the symptoms of PASC may not be a direct result of the SARS- CoV- 2 virus but may be the result of the reactivation of latent human herpesviruses. Peluso et al. at UCSF reported that EBV reactivation is associated with fatigue and neurocognitive dysfunction in patients with PASC (Peluso, 2022). Reactivation of EBV has been reported among the critically ill patients suffering from PASC and EBV viremia has been correlated with COVID severity (Naendrup, 2022; Paolucci, 2021; Simonnet, 2021; Gold, 2021; Vojdani, 2023). A longitudinal multi- omic** study **suggested that four main risk factors for developing PASC are type** ~~is not required to be submitted to the IND. 16 PRID~~ **2 diabetes, SARS** ~~201 Phase 2a Study of IMC~~ ~~1 In~~ **CoV- 2 RNAemia, specific auto- antibodies, and EBV viremia (Su, 2022).** Patients with ~~Fibromyalgia~~ **the post- COVID syndrome and reactivation of EBV and HHV- 6 infections are at high risk of developing various pathologies, including rheumatologic diseases** (~~NCT01850420~~ **Zubchenko, 2022**) ~~PRID~~ **. In July 2023, the Company received positive data from an exploratory, open** - **label, proof of concept** ~~201 Phase 2a Study DesignThe PRID- 201~~ study **in LC funded by** ~~represents the first placebo- controlled study evaluating the safety and~~ - **an unrestricted grant provided** ~~efficacy of IMC- 1. The Phase 2a clinical study involved 143 FM patients and a 16- week, multicenter, double blind, randomized, placebo- controlled, Phase 2a proof of concept trial conducted under IND 114827. Randomized patients received either IMC- 1 or placebo in a 1: 1 ratio. The primary objective of the study was~~ to ~~evaluate~~ the **Bateman Horne Center** ~~safety and efficacy of IMC- 1, as a single treatment for patients with primary FM. The primary efficacy outcome measure was a change from baseline in FM pain. FM pain was assessed using the 24- hour recall average pain score as recorded on the 11- point Numerical Rating Scale~~ (" ~~NRS~~ **BHC** ") ~~measure during~~ **. BHC enrolled female patients diagnosed with LC illness, otherwise known as PASC. Patients (n- 22) treated with a combination of valacyclovir and celecoxib (" Val / Cel ") exhibited** ~~clinic~~ **clinically** ~~visits~~ **and statistically significant improvements in fatigue** , **pain, and symptoms of autonomic dysfunction** as well as **ratings of general well- being related to LC when treated open- label for 14 weeks, as compared to a control cohort (n = 17) of female LC patients matched by age and length of illness and treated** with **routine care** ~~the 7- day recall average pain score recorded on the Revised Fibromyalgia Impact Questionnaire (" FIQ- R ")~~ . The ~~safety~~ **statistically significant improvements in PASC symptoms** and ~~tolerability~~ **general health status were particularly encouraging given that the mean duration** of **LC illness** ~~treatment with IMC- 1~~ was ~~compared to~~ **two years for both the** ~~placebo by analysis of vital signs, laboratory parameters, treatment~~ - **treated** ~~- emergent adverse events (" TEAEs "),~~ and ~~discontinuation due~~ **control cohort prior** to ~~adverse events~~ **enrollment in this study** . A **summary** ~~complete description~~ of the ~~study, including secondary and exploratory objectives, and~~

results can be **seen below.** found in the PRID- 201 Clinical Study Report submitted to the Investigational New Drug **EndpointsP ValueH PROMIS Fatigue T- Score0. 008NRS Fatigue 0- 10 Scale < 0. 001NRS Pain 0- 10 Scale0. 041PGIC 1- 7** (" IND " **7 is best**) on December 11, 2014 (Serial No. 0009). Patients completed the NRS for pain, revised FIQ- R, Beck Depression Inventory (" BDI- II "), Multidimensional Fatigue Inventory (" MFI "), and the National Institutes of Health (" NIH ") Patient- Reported Outcomes Measurement Information System (" PROMIS ") fatigue questionnaire at Baseline and Weeks 6, 12, and 16 (or early termination (" ET ")). Patients also completed a Patient Global Impression of Change (" PGIC ") questionnaire at Weeks 6, 12, and 16 (or ET). IMC- 1 demonstrated statistically significant improvement in the chronic pain of the studied FM patients when measured by either metrics utilized in the study: the 24- hour recall data, or the 7- day pain recall. Additionally, in this proof- of- concept study, IMC- 1 treated subjects reported significant improvements on overall global impression of change at the 12 and 16- week visits. Significant improvement in fatigue (PROMIS fatigue scale) and mood (BDI- II scale) were noted at endpoint. The primary outcome measure was based on change in patient- reported pain scores from baseline to week 16 of the study. IMC- 1 treated subjects reported statistically significant better scores compared to placebo subjects, as summarized below. The two pain scales are very similar. The NRS scale measures pain over the last 24 hours on an 11- point numerical rating scale (from 0 = no pain to **. 022PGIC 0-** 10 = worst imaginable pain) that was recorded during clinic visits. The FIQ- R is a disease specific instrument designed to assess the impact of FM on various aspects of the patient' s well- being. The symptom section of the FIQ- R asks the patient to rate their level of pain over the past 7 days using an 11- point numerical scale (from 0 = No Pain to 10 = Unbearable Pain). PRID- 201 Phase 2a Primary Endpoint AnalysisPlacebo LSIMC- 1 LS Change @ Change @ Pain Analysis Endpoint (SE) Endpoint (SE) Contrast (SE) P- ValueNRS 24- hour recall, MMRM LOCF / BOCF Imputation @ 16 weeks- 1. 1 (0 **is best** . 28)- 1. 9 (0. 28)- 0. 8 (0. 37) 0. 031FIQ **019OISAS** - R 7 **Orthostatic Intolerance Symptoms Assessment Scale0. 002OIDAS** - days recall, MMRM LOCF **Orthostatic Intolerance Daily Activity Scale < 0. 001HADS depression0. 059HADS anxiety0. 02313 Treatment with Val** / **Cel was generally well tolerated** BOCF Imputation @ 16 weeks- 0. 92 (0. 30)- 2. 2 (0. 30)- 1. 25 (0. 38) 0. 001If the estimated change from baseline for a patient' s pain scores met or exceeded 50 %, **with an observed safety profile consistent with** they - **the** were considered a 50 % pain responder **known safety profiles of valacyclovir and celecoxib** . In the **study** pain responder analysis , **nausea** a generalized linear regression curve fit was applied to an individual patient' s pain data. The high hurdle of 50 % pain reduction from baseline is statistically significant at endpoint, pain outcome measures by 50 % responder analysis are summarized below. 17 PRID- 201 Phase 2a Secondary Endpoint 50 % Reduction of Pain Analyses with Curve FitPlaceboPlaceboIMC- 1 Responders Non- Responders Responders IMC- 150 % Pain Responder Analysis Measure (%) (%) (%) Non- Responders P - ValueWeek 16 Visit, 50 % Reduction NRS 11 (15. 1) 62 (84. 9) 20 (30. 3) 46 (69. 7) 0. 009Week 16 Visit, 50 % Reduction FIQ - R Pain 12 (16. 9) 59 (83. 1) 25 (37. 9) 41 (62. 1) 0. 001As shown in the chart below, the same analysis was performed for a 30 % reduction in pain, and the results were statistically significant for the responders with 7- day recall but were not statistically significant for the 24- hour NRS. PRID- 201 Phase 2a Secondary Endpoint 30 % Reduction of Pain Analyses with Curve Fit PlaceboPlaceboIMC- 1 RespondersNon- RespondersRespondersIMC- 130 % Pain Responder Analysis Measure (%) (%) (%) Non- Responders P- ValueWeek 16 Visit, 30 % Reduction NRS 23 (31. 5) 50 (68. 5) 28 (42. 4) 38 (57. 6) 0. 052Week 16 Visit, 30 % Reduction FIQ- R Pain 20 (28. 2) 51 (71. 8) 29 (43. 9) 37 (56. 1) 0. 012Past studies of FM treatment have indicated that the Patient Global Interpretation Change (PGIC) scale is a sensitive measure for detecting therapeutic benefit. While it tends to correlate most **common** closely with pain results, the PGIC can be viewed as a patient' s assessment of overall therapeutic benefit of the therapy in question. The PGIC outcome measure was pre- specified as a key secondary endpoint. The PGIC responder analysis (see below) was significant at the 6, 12, and 16- week visits. PRID- 201 Phase 2a Secondary Endpoint Patient Global Impression of Change ResultPlaceboPlaceboIMC- 1RespondersNon - RespondersRespondersIMC- 1PGIC Analysis (%) (%) (%) Non - Responders P- ValueWeek 6 Visit 14 (19. 2) 59 (80. 8) 26 (37. 7) 43 (62. 3) 0. 040Week 12 Visit 13 (17. 8) 60 (82. 2) 26 (37. 7) 43 (62. 3) 0. 005Week 16 Visit 14 (19. 2) 59 (80. 8) 23 (33. 3) 46 (66. 6) 0. 040FIQ- R total score change was significant as was the PROMIS Fatigue inventory, both of which evidence that IMC- 1 does more than just modify the perception of pain. The FIQ- R total score is a composite of all questions from all three domains (Functional, Overall Impact and Symptoms). Fatigue was assessed in both the PROMIS fatigue score and the MFI total score. In the statistical analyses, the reductions from Baseline to Week 16 were numerically greater in the IMC- 1 group than in the placebo group and reached statistical significance for the reduction in fatigue score in the PROMIS assessment (LS mean change of- 2. 68 vs.- 6. 65, p = 0. 001) but not in the MFI total score assessment (LS mean change- 3. 69 vs.- 6. 90, p = 0. 107). 18 PRID- 201 Phase 2a Secondary Endpoint Fibromyalgia Impact Questionnaire- Revised & PROMIS Fatigue Results PlaceboIMC - 1Placebo LSIMC - 1 LS Outcomes Measure Method Baseline Baseline Change (SE) Change (SE) Contrast (SE) P - ValueFIQ- R Week 16 MMRM LOCF / BOCF 56. 81 (73) 54. 28 (69)- 7. 87 (2. 33)- 17. 54 (2. 40)- 9. 67 (3. 05) 0. 002PROMIS Fatigue Week 16 MMRM LOCF / BOCF 65. 83 (73) 65. 55 (69)- 2. 68 (0. 93)- 6. 65 (0. 96)- 3. 96 (1. 22) 0. 001The FIQ- R demonstrated statistical significance in all 3 domains (see below). Analysis of FIQ- R Domain Scores with LOCF / BOCF ImputationWeek 16LS Mean (SE) Change from Baseline FIQ- R AnalysisPlaceboIMC - 1LOCF / BOCF Imputation) * N = 71 N = 66 Contrast (SE) P- Value * * Functional Domain- 5. 44 (2. 32)- 14. 29 (2. 40)- 8. 85 (3. 03) 0. 004Overall Impact Domain- 1. 89 (0. 61)- 4. 29 (0. 63)- 2. 40 (0. 79) 0. 003Symptoms Domain- 7. 90 (2. 33)- 16. 77 (2. 40)- 8. 88 (3. 06) 0. 004 * LOCF / BOCF imputation = BOCF for missing data due to withdrawals related to adverse events or lack of efficacy or LOCF for missing data unrelated to efficacy or adverse events. * * Obtained from MMRM model with treatment as the main effect, and investigative site and Baseline score as covariates. Use of Rescue MedicationTramadol use was prospectively identified as the only rescue therapy to be used in this study. The proportion of patients taking tramadol for FM rescue was defined as all tramadol usage from the concomitant medication logs. The proportion of patients who took rescue therapy for FM was summarized by treatment group. The use of tramadol was significantly higher in the placebo group compared to the IMC- 1 group. 19 IMC- 1 exhibited consistent improvement across several secondary FM treatment outcomes, including functional assessments, lower fatigue, increased time

to rescue medication and improvements in FM patient' s global health status, as reflected in the table below. PRID- 201 Phase 2a SafetyTolerability of IMC- 1 was better than placebo in Study PRID- 201 (P2a). As shown below, many of the treatment- emergent adverse event categories, including gastrointestinal, were reported more frequently in the placebo group and are actually symptoms of FM. No serious unexpected adverse events were noted in this study . There were no deaths during the study and only three serious adverse events **observed** (" SAEs ") were reported. The two SAEs in **this study** the IMC- 1 group were a Non- ST- Segment Elevation Myocardial Infarction and **only** a Facial Cellulitis and the one **treated patient discontinued treatment due to adverse events,** placebo group SAE was a right breast micro- metastatic ductal carcinoma. One of the three SAEs was considered possibly related to **drug treatment. In August 2023, we signed an unrestricted grant research agreement with BHC to conduct a second, investigator- initiated, randomized, double- blinded, placebo- controlled** study **of LC** treatment — the non- ST- segment elevation myocardial infarction that occurred early in the study in a 47- year- old patient treated with IMC- 1 **2** . The causal relationship of this SAE **planned enrollment target is 60 female patients randomized** to **one of three** treatment with IMC- 1 cannot **arms. Patient enrollment commenced in December 2023 and we project results to** be **available in** ruled out; however, the patient' s underlying coronary artery disease and strong family history of premature cardiac disease suggest that other -- **the second half** causal factors were also involved. PRID- 201 Phase 2a Adverse Event ReportAdverse Events Reported for ≥ 5 % of **2024** the Patients in Either Treatment GroupPlaceboIMC - 1 Adverse Event N = 73 N = 69 Any Event 57 (78 . **BHC is a** 1) % 50 (72. 5) % Headache 10 (13. 7) % 8 (11. 6) % Urinary Tract Infection 4 (5. 5) % 6 (8. 7) % Blood Lactate Dehydrogenase Increased 1 (1. 4) % 4 (5. 8) % Nasopharyngitis 1 (1. 4) % 4 (5. 8) % Diarrhea 9 (12. 3) % 3 (4. 3) % Nausea 13 (17. 8) % 3 (4. 3) % Fibromyalgia 4 (5. 5) % 2 (2. 9) % Vomiting 5 (6. 8) % 2 (2. 9) % 20 Adverse Events Reported for ≥ 5 % of the Patients in Either Treatment GroupPlaceboIMC - 1Adverse Event N = 73 N = 69Constipation 6 (8. 2) % — Gastroesophageal Reflux Disease 4 (5. 5) % — Alopecia 4 (5. 5) % — Oropharyngeal Pain 4 (5. 5) % — In PRID- 201 Phase 2a, as seen in the chart below, more patients in the placebo group (16. 2 %; n = 12) discontinued therapy due to adverse events than on **non** IMC - **profit, interdisciplinary Center of Excellence advancing the diagnosis and** 1 (5. 8 %; n = 4). Increased treatment adherence in actual clinical practice is important in any chronic therapy. The lack of adherence to currently available treatments is indicative of the significant need for more effective and better tolerated therapies. Patients and physicians suggest that an ideal treatment would have fewer side effects and address the pervasive symptoms of FM including chronic fatigue ; **disorders including myalgic encephalomyelitis /** chronic fatigue **syndrome,** was one of the three key factors of an ideal FM product that was discussed at the FM PFDD meeting **, post- viral syndromes, and related comorbidities** . The preliminary **We expect the results from this study will help inform the final** clinical **design** evidence reported suggests the potential for IMC- 1 to address an unmet medical need by first treating an underlying cause, and thereby the symptoms of FM. IMC- 1 also has the potential to improve safety and tolerability through more manageable rates of adverse reactions and consequently improving efficacy through improved adherence by FM patients. IMC- 1 Phase 2a End of Study Blinded QuestionnaireAn end of study questionnaire analysis was included as an exploratory instrument in this Phase 2a study. It simply asked the patients whether they had suffered any conditions listed below which are commonly associated with FM, and if so, how their symptoms were now relative to baseline. The likelihood of improvement versus placebo was measured for patients on IMC- 1 in the blinded " End of PRID- 201 Phase 2a Trial " Questionnaire; data listed below: ● FM and Chronic Fatigue: 2. 2 times (improvement vs placebo) ● IBS: 2. 8 times ● Brain Fog (cognitive impairment): 2. 1 times ● Headache: 2. 5 times21 ● Temporomandibular joint: 5 times ● Insomnia: 1. 7 times ● Neck and back pain: 2. 3 times ● Anxiety: 2. 8 times ● Depression: 1. 6 timesThis information was gathered as exploratory data to inform future research. For example, patients who were on IMC- 1 and had IBS symptoms were 2. 8 times more likely to be improved compared to placebo. IBS is one of the indications we may explore for future IMC- 1 clinical trials. PRID- 202 Phase 2b FORTRESS Study of IMC- 1 In Patients with Fibromyalgia (NCT04748705) PRID- 202 Phase 2b FORTRESS Study DesignIn May 2021, we began screening patients in our Phase **planned LC** 2b study known as the FORTRESS study (an abbreviation that stands for Fibromyalgia Outcome Research Trial Evaluating Synergistic Suppression of Herpes Virus) and in June 2021, we announced the dosing of our first patient in the FORTRESS study . The study participants were randomized to receive either IMC- 1 or placebo in a 1: 1 ratio. FORTRESS was a double- blinded, randomized, placebo- controlled, trial of IMC- 1 for the treatment of FM. A total of 425 female FM patients ages 18 to 65 were randomized in a 1: 1 ratio to treatment with either IMC- 1 or placebo at 42 U. S. sites. The primary endpoint for our FORTRESS study was reduction in pain over time. Patients were dosed with IMC- 1 (675 mg famciclovir and 180 mg celecoxib) or matching placebo on a BID basis for 14 weeks. At the Week 14 primary endpoint visit, all patients were switched to placebo on a blinded basis. Previous experience with chronic pain trials has indicated that efficacy outcome measures recorded at the final study visit may be confounded by psychological factors relating to patients exiting a study. Therefore, it was critical that the patient was unaware of this potential change in her assigned study drug during the Week 14 and Week 16 interval. The primary objective of the study was to evaluate the safety and efficacy of IMC- 1, as a single treatment for patients with primary FM. The primary efficacy outcome measure was pain reduction. The patient' s self- reported 24- hour recall pain intensity score was evaluated on the 11- point Numerical Rating Scale (" NRS ") measure collected daily on an e- diary. Weekly mean scores were calculated from averaging the available daily scores recorded for that week. The safety and tolerability of treatment with IMC- 1 was compared to placebo by analysis of vital signs, laboratory parameters, treatment- emergent adverse events (" TEAEs "), and discontinuation due to adverse events. A complete description of the study, including secondary and exploratory objectives, and results can be found in the PRID- 202 Clinical Study Report that will be submitted to the Investigational New Drug (" IND ") in Q2 of 2023. Pain reduction was measured daily on the NRS 24- hour recall scale via an electronic diary that the patient used at home. In addition to assessing the FM patient' s pain reduction, we also assessed IMC- 1' s ability to improve symptoms of fatigue, sleep disturbance, overall global health status and patient function. In parallel to the FORTRESS study, our chronic toxicology studies in two species were completed. These studies are required by regulatory **Regulatory and** authorities to support chronic administration of IMC- 1 in future clinical development **Development**

TimelineIMC ~~. Patients completed the NRS for pain daily on an electronic diary, the revised FIQ - R, the Beck Depression Inventory (" BDI- II "), the National Institutes of Health (" NIH ") Patient- Reported Outcomes Measurement Information System (" PROMIS ") fatigue and sleep questionnaires and the Hospital Anxiety and Depression Scale (" HADS ") at Baseline and Weeks 6, 12, 14 and 16 (or early termination (" ET ")) during clinic visits. Patients completed a Patient Global Impression of Change (" PGIC ") questionnaire at Weeks 6, 12, 14 and 16 (or ET) during clinic visits. 22 PRID- 202 Phase 2b FORTRESS Study ResultsIn this study, IMC- 1 had a greater reduction in FM related pain at each study visit but did not achieve statistically significant improvements compared to placebo at the Week 14 primary endpoint. The graph below shows the primary endpoint result, p = 0. 30: However, an anomalous bifurcation of results was noted when comparing the patients enrolled during the first half of the study (" Cohort 1 ") with results from patients enrolled during the second half of the study (" Cohort 2 "). More specifically, there were no statistically significant differences between treatment with IMC- 1 versus placebo for Cohort 1 patients on any of the outcome measures of interest. Conversely, there were statistically significant differences in multiple outcomes of interest including the primary endpoint of reduction in pain at Week 14 as compared to placebo, p = 0. 030. The graph below compares Cohort 1 to Cohort 2 on the primary endpoint: 23 Other outcomes that were statistically significant in Cohort 2 included fatigue (p = 0. 006), PGIC mean score change (p = 0. 027), FIQ- R symptoms (p = 0. 015), and FIQ- R total score change (p = 0. 019). It is highly unlikely that the differences between the first half and second half study results could be a random finding. In addition to the Cohort 1 vs Cohort 2 finding, there was a subpopulation recruited through social media advertising (who were consequently new to the staff at the treatment sites and who were not prior FM trial participants), who also showed statistically significant results on both the primary endpoint and multiple secondary endpoints, independent of Cohort timing. The Table below summarizes the clinical results for the 175 patients included in this advertising subpopulation: Advertising Population Outcomes AnalysisP ValueEffect SizePGIC mean score change0. 0050. 43PROMIS fatigue0. 0010. 49FIQ- R symptoms domain0. 0060. 42FIQ- R total score0. 0050. 43Pain interference0. 0310. 33PROMIS sleep0. 0770. 27HADS depression0. 0020. 48HADS anxiety0. 0110. 39BDI- II0. 0100. 39While the overall efficacy results from FORTRESS did not achieve statistical significance, the safety results were consistent with the excellent results previously seen in the Phase 2a study. As was seen previously, dropout rates on drug were less than placebo, and all adverse event categories other than COVID- 19 infection were less than 5 %. The Table below compares adverse event rates between IMC- 1 and placebo: Adverse EventPlaceboN = 208IMC- 1N = 216COVID- 19 infection 17 (8. 2 %) 20 (9. 3 %) Headache 12 (5. 8 %) 8 (3. 7 %) Nausea 4 (1. 9 %) 8 (3. 7 %) Urinary tract infection 10 (4. 8 %) 7 (3. 2 %) Sinusitis 7 (3. 4 %) 7 (3. 2 %) Diarrhea 7 (3. 4 %) 7 (3. 2 %) Upper respiratory tract infection 1 (0. 5 %) 7 (3. 2 %) Dyspepsia 3 (1. 4 %) 5 (2. 3 %) Depression 2 (1. 0 %) 5 (2. 3 %) Constipation 2 (1. 0 %) 4 (1. 9 %) Cough 2 (1. 0 %) 4 (1. 9 %) Urine protein / creatinine ratio increased 1 (0. 5 %) 4 (1. 9 %) Anxiety 1 (0. 5 %) 4 (1. 9 %) Glomerular filtration rate decreased 3 (1. 4 %) 3 (1. 4 %) Fatigue 1 (0. 5 %) 3 (1. 4 %) Alanine aminotransferase increased 0 (0. 0 %) 3 (1. 4 %) Based on the analysis of the FORTRESS data, we believe focusing the forward development of IMC- 1 on New FM patients represents a viable and manageable path forward. We~~ **1We** ~~are scheduled~~ **have continued** to ~~meet with~~ **regularly engage** the FDA **regarding** ~~in March 2023 to discuss the most appropriate next steps in advancing IMC- 1 development as a treatment for FM. If alignment can be reached, management will consider raising additional capital to fund future research and / or seek a partner to develop or co- develop IMC- 1 as a treatment for FM. 24 Regulatory and Development TimelineWe have regularly engaged the FDA on IMC- 1 for the treatment of FM. The FDA has provided the following guidance with respect to the development of~~ IMC- 1 for the treatment of FM. Since we are combining proprietary doses of two previously approved drugs, our fixed dose combination product ~~candidate~~ **candidates** ~~is~~ **are** eligible for submission to the FDA for approval under Section 505 (b) (2) of the Federal Food, Drug and Cosmetic Act (" FDCA "). ~~Section 505 (b) (2) permits the submission of an NDA where at least some of the information required for approval comes from studies that were not conducted by, or for, the applicant and on which the applicant has not obtained a right of reference. The 505 (b) (2) application enables us to reference published literature and / or the FDA' s previous findings of safety and effectiveness for previously approved drugs with the same active ingredient.~~ Under Section 505 (b) (2), we ~~plan~~ **are able** to rely upon FDA' s previous findings of safety and effectiveness, and extensively reference several sections of the ~~US~~ **United States** Prescribing Information for Famvir (famciclovir) ~~, from Novartis,~~ and Celebrex (celecoxib) ~~, from Pfizer, the reference drugs for our program~~ . ~~The~~ **We expect our** 505 (b) (2) NDA filing ~~will~~ **to** rely on portions of the development programs conducted **for** ~~by the sponsors of~~ the reference drugs, as described in the FDA- approved ~~US~~ **United States** Prescribing Information. ~~The~~ **In our discussions with the FDA, the** FDA has agreed to our **505** (b) (2) filing plan. At the conclusion of our **FORTRESS** Phase ~~2a~~ **2b** clinical study in ~~2017~~ **2022,** we ~~held~~ **requested** an end- of- phase 2 meeting with the FDA ~~and conducted a subsequent conference call~~ **. The meeting was held in March 2023,** with the **Anesthesiology, Addiction Medicine and Pain Medicine division of the** FDA ~~in November 2017~~ . ~~As~~ **Based on** a ~~result~~ **review** of ~~those~~ -- **the** ~~meetings~~ **safety and efficacy data,** the FDA ~~has~~ provided **feedback that our** ~~us with a defined path forward to~~ Phase 3 ~~, including agreement~~ **proposal was acceptable. The proposed Phase 3 program will consist of four primary components:** ~~to~~ **two** ~~initiate~~ **adequate and well- controlled clinical studies, one of which would be** a **full factorial design with each of the individual components of IMC- 1 (famciclovir and celecoxib) as separate comparator arms, a long- term safety trial, and a pharmacokinetic / food effect study. Based on data from the recently completed FORTRESS** Phase 2b ~~study and / or~~ **trial, we proposed a** Phase 3 **development program targeting community- based FM patients, who have not participated in prior FM** ~~trial~~ **trials** ~~after we provide animal~~ **. The FDA was in agreement and the Company could progress to Phase 3 subject to review of the final results from our recently completed chronic** toxicology **program** ~~study data, conduct a human PK study with celecoxib and famciclovir combined in one tablet (which has been completed) and submit the Phase 2b clinical trial protocol that includes monitoring renal function through standard safety labs to the FDA~~ . The ~~human PK study on the new tablet, using a three- way crossover study design, has been successfully completed. IMC- 1 performed as expected in the human PK study, with no drug- drug interactions and no reported adverse events. Multiple dose PK of IMC- 1 has been well characterized and provides~~

~~additional data to better understand the PK profile of IMC- 1. We have also successfully completed the required 90- day sub-~~ chronic toxicology studies **consisted** ~~with the oral combination~~ of ~~IMC~~ **a six** ~~-~~ ~~1~~ **month rat and a nine- month dog study. The final reports were completed in May 2023 and submitted to the FDA** that **month** ~~we believe support the optimal dosing used in our FORTRESS study and to be used in our Phase 3 trials~~ . **Results** ~~This GLP 13- week general toxicology study with toxicokinetics and a recovery period has been completed, as has a 13- week GLP study of embryo- fetal development in rats, including using higher famciclovir doses. There were no unexpected toxicities from IMC- 1 (all toxicities shown~~ were consistent with ~~the known toxicities of the individual reference drugs -- celecoxib and famciclovir). Based on its review of prior 90- day and chronic toxicology studies, the FDA is requesting that we assess long term testicular and kidney toxicity in our chronic toxicology studies. In order to support chronic long- term dosing with IMC- 1, we conducted the required chronic toxicology studies in parallel to the FORTRESS study. These studies consisted of a six- month rat and a nine- month dog study. Consistent with~~ earlier studies, **and all** ~~there were no unexpected toxicities from IMC- 1. All~~ toxicities shown were consistent with known toxicities ~~in~~ **of** celecoxib and famciclovir. The ~~development of~~ **data were reviewed by the FDA and following** ~~the~~ **their initial review of our chronic toxicology program, the FDA concluded that the chronic toxicology studies appear adequate to support the safety of** IMC- 1 ~~tablet formulation and manufacture was completed~~ at ~~Frontida (Aurora, IL) along with the ongoing stability data (18- month stability data completed). The IMC- 1 prototype tablet, completed at Catalent, had excellent 24- month stability. In September 2022, we announced the top line results from our FORTRESS Phase 2b FM study. Analysis of the study data revealed: ● New FM patients treated with IMC- 1, who were recruited into our FORTRESS study through social media advertising, demonstrated statistically significant reductions in FM related pain, fatigue, anxiety and depressive symptoms and showed an overall improvement in their -- **the dose proposed by the Company** ~~global health status. 25 ● Prior FM patients, who had previously enrolled in FM studies and / or~~ **for chronic use.** ~~who had a prior relationship with~~ **With completion** ~~the FORTRESS study sites, did not exhibit meaningful treatment benefits. ● New patients treated with IMC- 1 also exhibited a lower discontinuation rate due to adverse events as compared with New patients receiving placebo. ● All patients treated with IMC- 1 demonstrated exemplary safety and tolerability in the FORTRESS study. We believe the safety and efficacy results from the FORTRESS study support progression~~ of **this initial review** ~~IMC- 1 to Phase 3 development for New patients, who represent the vast majority~~ of the **toxicology program,** ~~FM patient community. We are scheduled to meet with~~ the FDA ~~in March 2023 to discuss advancing IMC- 1 into Phase 3 development as~~ **has now agreed to our proposed** ~~a treatment for FM. At this meeting, we will discuss plans for a~~ Phase 3 program **for IMC- 1 for treatment of fibromyalgia. IMC- 2In September 2023, we requested a Pre- Investigational New Drug Application (" PIND ") for IMC- 2 for the treatment of LC with the FDA. In October, we submitted a full briefing package and by the end of December 2023, we received written communication from the Antivirals Group, Division of Infectious Diseases, on the development requirements and key endpoints associated with advancing IMC- 2 into Phase 2 for treatment of 14 LC symptoms. The FDA agreed** that **we** ~~would~~ **could** ~~support submission of~~ **use improvement in fatigue as** a ~~NDA for~~ **primary endpoint in a Phase 2 study and agreed with our overall study design. We are targeting the initiation of a Phase 2 program in LC in the second half of 2024. The Phase 2 study will compare** IMC- ~~1 for the treatment~~ **2 versus placebo in a randomized, double- blind study** of **LC patients for 12 weeks.** FM ~~.~~Market and CompetitionThe three pharmaceutical agents currently approved for the treatment of FM, pregabalin (Lyrica), duloxetine (Cymbalta) and milnacipran (Savella), are all associated with significant adverse events and limited clinical efficacy. Despite this, Lyrica and Cymbalta together had peak sales of approximately $ 10 billion across all of their approved indications, with Lyrica achieving sales of $ 3. 6 billion in the United States in 2018, including sales related to FM. Reflecting the need for more effective and better tolerated treatments, a large number of additional products are also prescribed that are not indicated for FM. The American Academy of Rheumatology and FDA strongly recommends avoiding opioid narcotic medications for treating FM. Evidence shows these drugs are not helpful to most people with FM and will cause greater pain sensitivity or make pain persist. Despite that, research shows that FM patients are prescribed opioids as part of their treatment regimen. According to the National Fibromyalgia & Chronic Pain Association, approximately 10 million Americans and 3 % – 6 % of people worldwide are afflicted with FM. Common chronic pain conditions affect approximately 116 million adults in the United States at a cost of $ 560 – $ 635 billion annually in direct medical treatment costs and lost productivity. This estimate combines the incremental cost of health care ($ 261- $ 300 billion) and the cost of lost productivity ($ 299 – $ 335 billion), more than heart disease or cancer. Competitive late- stage FM pipeline products are not disruptive to the current standard of care, nor do they appear to address the root cause of the disease. ~~We conducted a commercial opportunity assessment in each of 2014 and 2020 to better understand the medical needs existing in the FM treatment market and to quantify the addressable market opportunity for a potential new FDA approved FM treatment. Our 2014 assessment reviewed the competitive landscape for the treatment of FM, including physician demographic information, patient demographic information, current & potential future treatment projections, and obtained information from high prescribing physicians and primary research with six healthcare payors as well as conducted a revenue forecast. Our 2020 assessment provided an updated disease review, forecast and valuation for FM and IBS for the U. S. and Ex- U. S. markets. Both assessments show that significant unmet medical needs exist in the FM treatment armamentarium, as well as the IBS treatment armamentarium, highlighting the commercial potential for a new medicine that proves to be safe and effective as determined by the FDA. 26 Primary Research BackgroundIn our 2014 assessment 75 physicians were surveyed, targeting high volume prescribers in key geographies and practice settings (rheumatologists, pain specialists, neurologists, primary care) across the United States. Also, eight high prescribing key opinion leader physicians (" KOLs ") were interviewed to gain qualitative insights into the treatment paradigm for FM and related disorders. Additionally, six payors were interviewed to determine their receptivity to IMC- 1 as a first line treatment, how price sensitive these payors would be, how likely they would be to reimburse IMC- 1, and whether Medicare would cover IMC- 1. This primary research confirmed the large unmet medical need in the treatment of FM. The researchers found that physicians and patients, express a need for additional, safer and more efficacious FM therapy options. The 2014~~

~~assessment found that only 15 % of the 75 physicians surveyed expressed satisfaction with their current FM treatment options and none responded as being " very satisfied ". Ninety- five percent of physicians surveyed indicated the available standard of care treatments only manage symptoms and did not treat the cause of the disease. Physician Satisfaction with Available FM Therapies (n = 75) Physicians paralleled the concerns described by the patients at FDA' s PFDD meeting indicating that the currently FDA approved therapies have many of the associated adverse events such as dizziness, nausea or vomiting, weight gain, dry mouth, sleeplessness, restlessness, peripheral edema, chronic headaches, IBS symptoms and suicidal thoughts or actions. The six payors interviewed confirmed FM to be a serious disease with patients routinely consuming substantial healthcare resources. IMC- 1, with proprietary dosing (dosing cannot be replicated by generic products) and a unique antiviral MOA with Fast Track status, can be expected to receive favorable pricing and formulary coverage and a high level of unmet need exists because the underlying cause is not well understood and treatment is patchwork. Secondary Research: FM PipelineBoth of our 2014 and 2020 assessments analyzed historical markets for FM and related disorders and identified key players and trends. They also created competitive intelligence on all in- line and pipeline FM treatments, including ongoing U. S. clinical trials. It is worth noting that the mechanistic approach for all of these potential new treatment candidates is complementary to the antiviral IMC- 1 mechanistic approach, thus not true competitors to IMC- 1, presuming continued success. 27 Other Market OpportunitiesEach of the 2014 and 2020 assessment confirmed that FM represents an unmet medical need with a large market opportunity and that IMC- 1 is a differentiated product. Overall, the assessment found that physicians are not satisfied with current FM treatments, that the etiology and cause of FM remains poorly understood, and that current products only manage the symptoms of FM. We believe our paradigm changing discovery that herpes virus could play an important role in the pathogenesis of FM. If successfully proven, we believe that IMC- 1 can be disruptive to the market and can change the way FM is treated. Furthermore, there is increasing recognition in the scientific community of the potential role of activated viruses, triggering a wide range of morbidities, including FM, IBS, fatigue related disorders and potentially dementia and even long Covid (" Long- COVID ") symptoms. The Company provided the Bateman Horne Center (" BHC ") with an unrestricted grant for an investigator- sponsored study to explore the therapeutic potential of combination antiviral therapy with Virios' second development candidate, IMC- 2, a combination of valacyclovir and celecoxib. The study is evaluating changes in common Long- COVID symptoms such as fatigue, sleep, attention, pain, autonomic function and anxiety and commenced dosing in the third quarter of 2022. The study is fully enrolled with data expected in mid- 2023.~~ Intellectual PropertyWe strive to protect and enhance the proprietary technologies, inventions and improvements that we believe are important to our business, including seeking, maintaining and defending patent rights, whether developed internally or licensed from third parties. Our policy is to seek to protect our proprietary position by, among other methods, pursuing and obtaining patent protection in the United States and in jurisdictions outside of the United States related to our proprietary technology, inventions, improvements, platforms and our product candidates that are important to the development and implementation of our business. As of December 31, ~~2022~~ **2023** , our portfolio of owned patents totaled 21 issued patents in the United States and abroad. This includes three Composition of Matter patents, including a Synergistic Patent, and two Method of Use patents in the United States, all of which relate to IMC- 1. Exclusivity with all patents extends to 2033. Issued US IMC- 1 Patents ● U. S. " Composition of Matter " Patents (US 8, 809, 351 & US 10, 034, 846) Drug- combination of famciclovir and celecoxib ● U. S. " Method- of- Use " Patent (US 9, 040, 546) Famciclovir celecoxib for the treatment of FM (fibromyalgia), CFS or IBS ● U. S. " Method- of- Use " Patent (US 9, 173, 863) Method of dispensing famciclovir celecoxib in a regimen to treat Functional Somatic Syndrome conditions ● U. S. " Composition of Matter " Synergistic Patent (US 10, 251, 853) Synergistic combination for total daily dose of famciclovir and ~~celecoxibIssued~~ **celecoxib15 Issued** Foreign IMC- 1 Patents ● European Patent (EP 2 811 833 & 2 965 759 – validated in 18 countries) ● Japan (JP 5855770 & 6422848) ● Australia (AU 2013217110) ~~28~~ ● China (CN 104144606) ● Korea (KR 10- 1485748) ● Canada (2, 863, 812) U. S. Patents Covering Other Anti- Viral Combinations ● U. S. 9, 682, 051 (acyclovir / meloxicam) ● U. S. 8, 623, 882 (acyclovir / diclofenac) ● U. S. 9, 259, 405 (famciclovir / diclofenac) ● U. S. 9, 642, 824 (valacyclovir / diclofenac) ● U. S. 9, 980, 932 (valacyclovir / meloxicam) ● U. S. 10, 543, 184 (acyclovir / celecoxib) ● U. S. 10, 632, 087 (famciclovir / meloxicam) ● U. S. 11, 096, 912 (valacyclovir / celecoxib) **U. S. Pending Applications ● U. S. provisional application Serial No. 63 / 524, 391 (valacyclovir / celecoxib or famciclovir / celecoxib to treat Alzheimer' s disease or Long- COVID) ● PCT / US2023 / 032842 (valacyclovir / celecoxib or famciclovir / celecoxib to treat Alzheimer' s disease or Long- COVID)** Individual patents extend for varying periods depending on the date of filing of the patent application or the date of patent issuance and the legal term of patents in the countries in which they are obtained. Generally, patents issued for regularly filed applications in the United States are granted a term of 20 years from the earliest effective non- provisional filing date. In addition, in certain instances, a patent term can be extended to recapture a portion of the U. S. Patent and Trademark Office (" USPTO ") delay in issuing the patent as well as a portion of the term effectively lost as a result of the FDA regulatory review period. However, as to the FDA component, the restoration period cannot be longer than five years and the total patent term including the restoration period must not exceed 14 years following FDA approval. The duration of foreign patents varies in accordance with provisions of applicable local law, but typically is also 20 years from the earliest effective filing date. However, the actual protection afforded by a patent varies on a product- by- product basis, from country to country and depends upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory- related extensions, the availability of legal remedies in a particular country and the validity and enforceability of the patent. **16** Furthermore, we rely upon trade secrets and know- how and continuing technological innovation to develop and maintain our competitive position. We seek to protect our proprietary information, in part, using confidentiality agreements with our collaborators, employees and consultants and invention assignment agreements with our employees. We also have confidentiality agreements or invention assignment agreements with our collaborators and selected consultants. These agreements are designed to protect our proprietary information and, in the case of the invention assignment agreements, to grant us ownership of technologies that are developed through a relationship with a third party. These agreements may be breached,

and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our collaborators, employees and consultants use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know- how and inventions. We have also been granted additional U. S. and EU patents, representing all possible combinations of targeted antivirals and non- steroidal anti- inflammatory drugs (NSAIDs / COX- 2s) containing appropriate COX- 2 & COX- 1 inhibition. At present, we are developing only IMC- 1 (famciclovir / celecoxib) with the other ~~29~~ patents being obtained to increase the therapeutic combinations that we may explore in the future to treat other virally medicated illnesses. Our commercial success will also depend in part on not infringing upon the proprietary rights of third parties. It is uncertain whether the issuance of any third- party patent would require us to alter our development or commercial strategies, or our drugs or processes, obtain licenses or cease certain activities. Our breach of any license agreements or failure to obtain a license to proprietary rights that we may require to develop or commercialize our future drugs may have an adverse impact on us. If third parties have prepared and filed patent applications prior to March 16, 2013 in the United States that also claim technology to which we have rights, we may have to participate in interference proceedings in the USPTO, to determine priority of invention. For more information, please see " Risk Factors — Risks Related to Our Intellectual Property. " Material AgreementsIn 2012, we entered into a Know- How License Agreement (the " License Agreement ") with the University of Alabama. In consideration for the License Agreement, the University of Alabama received membership interests in the Company representing 10 % of the issued membership interests at that time. The License Agreement is in effect for 25 years and will terminate on June 1, 2037. Under the License Agreement, we were granted a non- exclusive, worldwide, royalty- free license to utilize, including the right to sublicense and sell products incorporating, the know- how, technical information, and data related and pertaining to the herpesvirus biology, including herpesvirus replication mechanisms, modes of action of anti- herpesvirus medications, and sensitivity and accuracy of herpesvirus diagnostic tests, any of which were developed by the University of Alabama under the direction of Dr. Carol Duffy before the effective date of the License Agreement, all of which is defined as the Technical Information. The University of Alabama reserved the right to use the Technical Information for educational, research, clinical, and other non- commercial purposes. We may assign the license to any purchaser or transferee of substantially all of our assets. Sales and MarketingIf IMC- 1 **or IMC- 2** is approved, we plan to enter into sales and marketing agreements with one or several pharmaceutical companies to sell to neurologists, geriatric specialists and to primary care physicians. ManufacturingWe rely on third- party contractors for manufacturing clinical supplies and plan to do so for commercial amounts also. Presently we are working with an overseas supplier for the manufacture of the cGMP API and with a local supplier for the storage stability, encapsulating, blister packing, blinding and distribution of the capsules or pills to the clinical sites. **17** Government RegulationThe FDA and comparable regulatory authorities in state and local jurisdictions and in other countries impose substantial and burdensome requirements upon companies involved in the clinical development, manufacture, marketing and distribution of drugs, such as those we are developing. These agencies and other federal, state and local entities regulate, among other things, the research and development, testing, manufacture, quality control, safety, effectiveness, labeling, storage, record keeping, approval, advertising and promotion, distribution, post- approval monitoring and reporting, sampling and export and import of our product candidates. U. S. Government Regulation of Drug ProductsIn the United States, the FDA regulates drugs under the FDCA and its implementing regulations. The process of obtaining regulatory approvals and the subsequent compliance with applicable federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources. ~~30~~ Failure to comply with the applicable U. S. requirements at any time during the product development process, approval process or after approval, may subject an applicant to a variety of administrative or judicial sanctions, such as the FDA' s refusal to approve pending NDAs, withdrawal of an approval, imposition of a clinical hold, issuance of warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties. The process required by the FDA before a drug may be marketed in the United States generally involves the following: ● Completion of preclinical laboratory tests, animal studies and formulation studies in compliance with the FDA' s good laboratory practice (" GLP ") regulations. ● Submission to the FDA of an IND, which must become effective before human clinical trials may begin. ● Approval by an independent institutional review board (" IRB ") at each clinical site before each trial may be initiated. ● Performance of adequate and well- controlled human clinical trials in accordance with good clinical practice (" GCP ") requirements to establish the safety and efficacy of the proposed drug product for each indication. ● Submission to the FDA of an NDA. ● Satisfactory completion of an FDA advisory committee review, if applicable. ● Satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the product is produced to assess compliance with current good manufacturing practice (" cGMP ") requirements and to assure that the facilities, methods and controls are adequate to preserve the drug' s identity, strength, quality and purity. ● Satisfactory completion of FDA audits of clinical trial sites to assure compliance with GCPs and the integrity of the clinical data. ● Payment of user fees and securing FDA approval of the NDA. **18** ● Compliance with any post- approval requirements, including the potential requirement to implement a Risk Evaluation and Mitigation Strategy (" REMS ") and the potential requirement to conduct post- approval studies. Preclinical StudiesPreclinical studies include laboratory evaluation of product chemistry, toxicity and formulation, as well as animal studies to assess potential safety and efficacy. An IND sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data and any available clinical data or literature, among other things, to the FDA as part of an IND. Some preclinical testing may continue even after the IND is submitted. An IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to one or more proposed clinical trials and places the clinical trial on a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. As a result, submission of an IND may not result in the FDA allowing clinical trials to initiate. ~~31~~ Clinical TrialsClinical trials involve the administration of the investigational new drug to human subjects under the supervision of qualified investigators in accordance

with GCP requirements, which include the requirement that all research subjects provide their informed consent in writing for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. In addition, an IRB at each institution participating in the clinical trial must review and approve the plan for any clinical trial before it initiates at that institution. Information about certain clinical trials must be submitted within specific timeframes to the NIH for public dissemination on their www. clinicaltrials. gov website. Human clinical trials are typically conducted in three sequential phases, which may overlap or be combined: ● Phase 1: The drug is initially introduced into healthy human subjects or patients with the target disease or condition and tested for safety, dosage tolerance, absorption, metabolism, distribution, excretion and, if possible, to gain an early indication of its effectiveness. ● Phase 2: The drug is administered to a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage. ● Phase 3: The drug is administered to an expanded patient population, generally at geographically dispersed clinical trial sites, in well- controlled clinical trials to generate enough data to statistically evaluate the efficacy and safety of the product for approval, to establish the overall risk- benefit profile of the product, and to provide adequate information for the labeling of the product. Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and more frequently if serious adverse events occur. Phase 1, Phase 2 and Phase 3 studies or trials may not be completed successfully within any specified period, or at all. Furthermore, the FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB' s requirements or if the drug has been associated with unexpected serious harm to patients. **19** Marketing ApprovalAssuming successful completion of the required clinical testing, the results of the preclinical and clinical studies, together with detailed information relating to the product' s chemistry, manufacture, controls and proposed labeling, among other things, are submitted to the FDA as part of an NDA requesting approval to market the product for one or more indications. In most cases, the submission of an NDA is subject to a substantial application user fee. Under the Prescription Drug User Fee Act (" PDUFA "), guidelines that are currently in effect, the FDA has a goal of ten months from the date of " filing " of a standard NDA, for a new molecular entity to review and act on the submission. This review typically takes twelve months from the date the NDA is submitted to **the** FDA because the FDA has approximately two months to make a " filing " decision. In addition, under the Pediatric Research Equity Act of 2003, as amended and reauthorized, certain NDAs or supplements to an NDA must contain data that are adequate to assess the safety and effectiveness 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 also may require submission of a REMS plan to ensure that the benefits of the drug outweigh its risks. The REMS plan could include medication guides, physician communication plans, assessment plans, ~~32~~ and / or elements to assure safe use, such as restricted distribution methods, patient registries, or other risk minimization tools. The FDA conducts a preliminary review of all NDAs within the first 60 days after submission, before accepting them for filing, to determine whether they are sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in- depth substantive review. The FDA reviews an NDA to determine, among other things, whether the drug is safe and effective and whether the facility in which it is manufactured, processed, packaged or held meets standards designed to assure the product' s continued safety, quality and purity. The FDA may refer an application for a novel drug to an advisory committee. An advisory committee is a panel of independent experts, including clinicians and other scientific experts, which reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions. Before approving an NDA, the FDA typically will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities comply with cGMP requirements and are adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA may inspect one or more clinical trial sites to assure compliance with GCP requirements. After evaluating the NDA and all related information, including the advisory committee recommendation, if any, and inspection reports regarding the manufacturing facilities and clinical trial sites, the FDA may issue an approval letter, or, in some cases, a complete response letter. A complete response letter generally contains a statement of specific conditions that must be met in order to secure final approval of the NDA and may require additional clinical or preclinical testing for the FDA to reconsider the application. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. If and when those conditions have been met to the FDA' s satisfaction, the FDA will typically issue an approval letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. Even if the FDA approves a product, it may limit the approved indications for use of the product, require that contraindications, warnings or precautions be included in the product labeling, require that post- approval **20** studies, including Phase 4 clinical trials, be conducted to further assess a drug' s safety after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution and use restrictions or other risk management mechanisms under a REMS, which can materially affect the potential market and profitability of the product. The FDA may prevent or limit further marketing of a product based on the results of post- marketing studies or surveillance programs. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes, and additional labeling claims, are subject to further testing requirements and FDA review and approval. Special FDA

Expedited Review and Approval ProgramsThe FDA has various programs, including fast track designation, accelerated approval, priority review, and breakthrough therapy designation, which are intended to expedite or simplify the process for the development and FDA review of drugs that are intended for the treatment of serious or life- threatening diseases or conditions and demonstrate the potential to address unmet medical needs. The purpose of these programs is to provide important new drugs to patients earlier than under standard FDA review procedures. ~~33~~ To be eligible for a fast track designation, the FDA must determine, based on the request of a sponsor, that a product is intended to treat a serious or life- threatening disease or condition and demonstrates the potential to address an unmet medical need. The FDA will determine that a product will fill an unmet medical need if it will provide a therapy where none exists or provide a therapy that may be potentially superior to existing therapy based on efficacy or safety factors. The FDA may review sections of the NDA for a fast track product on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA, the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA. The FDA may give a priority review designation to drugs that offer major advances in treatment or provide a treatment where no adequate therapy exists. A priority review means that the goal for the FDA to review an application is six months, rather than the standard review of ten months under current PDUFA guidelines. Under the current PDUFA agreement, these six- and ten- month review periods are measured from the " filing " date rather than the receipt date for NDAs for new molecular entities, which typically adds approximately two months to the timeline for review and decision from the date of submission. Most products that are eligible for fast track designation are also likely to be considered appropriate to receive a priority review. In addition, products tested for their safety and effectiveness in treating serious or life- threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may be eligible for accelerated approval and may be approved on the basis of adequate and well- controlled clinical trials establishing that the drug product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality (IMM) that is reasonably likely to predict an effect on IMM or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA may require a sponsor of a drug receiving accelerated approval to perform post-marketing studies to verify and describe the predicted effect on IMM or other clinical endpoint, and the drug may be subject to accelerated withdrawal procedures. Moreover, under the provisions of the Food and Drug Administration Safety and Innovation Act ~~passed in July 2012~~ , a sponsor can request designation of a product candidate as a " breakthrough therapy. " A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life- threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Drugs designated as breakthrough therapies are also eligible for accelerated approval. The FDA must take certain actions, such as **21** holding timely meetings and providing advice, intended to expedite the development and review of an application for approval of a breakthrough therapy. Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. We may explore some of these opportunities for our product candidates as appropriate. Accelerated Approval PathwayThe FDA may grant accelerated approval to a drug for a serious or life- threatening condition that provides meaningful therapeutic advantage to patients over existing treatments based upon a determination that the drug influences a surrogate endpoint that is reasonably likely to predict clinical benefit. The FDA may also grant accelerated approval for such a condition when the product has an effect on an intermediate clinical endpoint that can be measured earlier than an effect on IMM, and that is reasonably likely to predict an effect on IMM or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments. Drugs granted accelerated approval must meet the same statutory standards for safety and effectiveness as those granted traditional approval. ~~34~~ For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign or other measure that is thought to predict clinical benefit but is not itself a measure of clinical benefit. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. An intermediate clinical endpoint is a measurement of a therapeutic effect that is considered reasonably likely to predict the clinical benefit of a drug, such as an effect on IMM. The FDA has limited experience with accelerated approvals based on intermediate clinical endpoints, but has indicated that such endpoints generally may support accelerated approval where the therapeutic effect measured by the endpoint is not itself a clinical benefit and basis for traditional approval, if there is a basis for concluding that the therapeutic effect is reasonably likely to predict the ultimate clinical benefit of a drug. The accelerated approval pathway is most often used in settings in which the course of a disease is long, and an extended period is required to measure the intended clinical benefit of a drug, even if the effect on the surrogate or intermediate clinical endpoint occurs rapidly. Thus, accelerated approval has been used extensively in the development and approval of drugs for treatment of a variety of cancers in which the goal of therapy is generally to improve survival or decrease morbidity and the duration of the typical disease course requires lengthy and sometimes large trials to demonstrate a clinical or survival benefit. The accelerated approval pathway is usually contingent on a sponsor' s agreement to conduct, in a diligent manner, additional post- approval confirmatory studies to verify and describe the drug' s clinical benefit. As a result, a drug candidate approved on this basis is subject to rigorous post- marketing compliance requirements, including the completion of Phase 4 or post- approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post- approval studies or confirm a clinical benefit during post- marketing studies, would 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. Orphan Drug Designation and ExclusivityUnder the Orphan Drug Act, the FDA may designate a drug product as an " orphan drug " if it is intended to treat a rare disease or condition (generally meaning that it affects fewer than 200, 000 individuals in the United States, or more in cases in which there is no

reasonable expectation that the cost of developing and making a drug product available in the United States for treatment of the disease or condition will be recovered from sales of the product). A company must request orphan product designation before submitting an NDA. If the request is granted, the FDA will disclose the identity of the therapeutic agent and its potential use. Orphan product designation does not convey any advantage in or shorten the duration of the regulatory review and approval process. **22** If a product with orphan status receives the first FDA approval for the disease or condition for which it has such designation or for a select indication or use within the rare disease or condition for which it was designated, the product generally will be receiving orphan product exclusivity. Orphan product exclusivity means that the FDA may not approve any other applications for the same product for the same indication for seven years, except in certain limited circumstances. If a drug or drug product designated as an orphan product ultimately receives marketing approval for an indication broader than what was designated in its orphan product application, it may not be entitled to exclusivity. Orphan exclusivity will not bar approval of another product under certain circumstances, including if a subsequent product with the same active ingredient for the same indication is shown to be clinically superior to the approved product on the basis of greater efficacy or safety, or providing a major contribution to patient care, or if the company with orphan drug exclusivity is not able to meet market demand. Further, the FDA may approve more than one product for the same orphan indication or disease if the products contain different active ingredients. Moreover, competitors may receive approval of different products for the indication for which the orphan product has exclusivity or obtain approval for the same product but for a different indication for which the orphan product has exclusivity. ~~35~~ Post- Approval RequirementsDrugs manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion and reporting of adverse experiences with the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims are subject to prior FDA review and approval. There are continuing, annual program user fee requirements for any marketed products. The FDA may impose a number of post- approval requirements as a condition of approval of an NDA. For example, the FDA may require post- marketing testing, including Phase 4 clinical trials, and surveillance to further assess and monitor the product' s safety and effectiveness after commercialization. In addition, drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments and list their marketed drug products with the FDA and state agencies and are subject to periodic unannounced inspections by the FDA and these state agencies for compliance with cGMP requirements. Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP requirements and impose reporting and documentation requirements upon the sponsor and any third- party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance. Once an approval of a drug is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in mandatory revisions to the approved labeling to add new safety information; imposition of post- market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things: ● Restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls. ● Fines, warning letters or holds on post- approval clinical trials. ● Refusal of the FDA to approve pending NDAs or supplements to approved NDAs, or suspension or revocation of product approvals. **23** ● Product seizure or detention, or refusal to permit the import or export of products. ● Injunctions or the imposition of civil or criminal penalties. The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Drugs or devices may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off- label uses, and a company that is found to have improperly promoted off- label uses may be subject to significant liability. U. S. Coverage and ReimbursementSignificant uncertainty exists as to the coverage and reimbursement status of our product ~~candidate~~ **candidates** , IMC- 1 **and IMC- 2** , or any other ~~development~~ **product** candidate for which we may seek regulatory approval. Sales in the U. S. will ~~36~~ depend in part on the availability of adequate financial coverage and reimbursement from third- party payors, which include government health programs such as Medicare, Medicaid, TRICARE and the Veterans Administration, as well as managed care organizations and private health insurers. Prices at which we or our customers seek reimbursement for our product candidates can be subject to challenge, reduction or denial by payors. The process for determining whether a payor will provide coverage for a product is typically separate from the process for setting the reimbursement rate that the payor will pay for the product. Third- party payors may limit coverage to specific products on an approved list or formulary, which might not include all the FDA- approved products for a particular indication. Also, third- party payors may refuse to include a branded drug on their formularies or otherwise restrict patient access to a branded drug when a less costly generic equivalent or another alternative is available ~~. Medicare Part D, Medicare' s outpatient prescription drug benefit, contains protections to ensure coverage and reimbursement for oral oncology products, and all Part D prescription drug plans are required to cover substantially all oral anti- cancer agents~~ . However, a payor' s decision to provide coverage for a product does not imply that an adequate reimbursement rate will be available. Private payors often rely on the lead of the governmental payors in rendering coverage and reimbursement determinations. Sales of IMC- 1 **, IMC- 2** or any other **product** candidates will therefore depend substantially on the extent to which the costs of our products will be paid by third- party payors. Achieving favorable coverage and reimbursement from the Centers for Medicare and Medicaid Services (" CMS ") and / or the Medicare Administrative Contractors is typically a significant gating issue for successful introduction of a new product. Third- party payors are increasingly challenging the price and examining the medical necessity and cost- effectiveness of

medical products and services, in addition to their safety and efficacy. In order to obtain coverage and reimbursement for any product that might be approved for marketing, we may need to conduct studies in order to demonstrate the medical necessity and cost- effectiveness of any products, which would be in addition to the costs expended to obtain regulatory approvals. Third-party payors may not consider our product candidates to be medically necessary or cost- effective compared to other available therapies, or the rebate percentages required to secure favorable coverage may not yield an adequate margin over cost or may not enable us to maintain price levels sufficient to realize an appropriate return on our investment in drug development. U. S. Healthcare Fraud and Abuse Laws and Compliance RequirementsWe are subject to various federal and state laws targeting fraud and abuse in the healthcare industry. These laws may impact, among other things, our proposed sales and marketing programs. In addition, we may be subject to patient privacy regulation by both the federal government and the states in which we conduct our business. The laws that may affect our operations include: ● the federal Anti- Kickback Statute, which prohibits, among other things, persons from soliciting, receiving, offering or paying remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, an item or service reimbursable under a federal healthcare program, such as the **24** Medicare and Medicaid programs. The term " remuneration " has been broadly interpreted to include anything of value; ● federal false claims and civil monetary penalties laws, including the federal civil False Claims Act, which prohibits anyone from, among other things, knowingly presenting, or causing to be presented, for payment to federal programs (including Medicare and Medicaid) claims for items or services that are false or fraudulent; ● provisions of the Health Insurance Portability and Accountability Act of 1996 (" HIPAA "), which created federal criminal statutes that prohibit, among other things, knowingly and willfully executing a scheme to defraud any healthcare benefit program or making false statements in connection with the delivery of or payment for healthcare benefits, items or services. In addition, HIPAA, as amended by the ~~37~~ Health Information Technology for Economic and Clinical Health Act and its implementing regulations, impose certain requirements relating to the privacy, security and transmission of individually identifiable health information; and ● the federal Physician Payment Sunshine Act requirements, under the Patient Protection and Affordable Care Act, which require manufacturers of certain drugs and biologics to track and report to CMS payments and other transfers of value they make to U. S. physicians and teaching hospitals as well as physician ownership and investment interests in the manufacturer. Many states have their own Sunshine laws governing the tracking and reporting of payments to healthcare providers. The Hatch- Waxman Amendments and Generic CompetitionSection 505 (b) (2) NDAsAs an alternative path to FDA approval for modifications to formulations or uses of products previously approved by the FDA, an applicant may submit an NDA under Section 505 (b) (2) of the FDCA. Section 505 (b) (2) was enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as " the Hatch- Waxman Amendments " to the FDCA and enables the applicant to rely, in part, on the FDA' s previous approval of a similar product, or published literature, in support of its application. Section 505 (b) (2) permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by, or for, the applicant and for which the applicant has not obtained a right of reference. If the Section 505 (b) (2) applicant can establish that reliance on FDA' s previous findings of safety and effectiveness is scientifically appropriate, it may eliminate the need to conduct certain preclinical studies or clinical trials of the new product. The FDA may also require companies to perform additional studies or measurements, including clinical trials, to support the change from the approved reference drug. The FDA may then approve the new product candidate for all, or some, of the label indications for which the reference drug has been approved or for any new indication sought by the Section 505 (b) (2) applicant. ANDA Approval ProcessThe Hatch- Waxman Amendments also established an abbreviated FDA approval process for drugs that are shown to be bioequivalent to drugs previously approved by the FDA through the NDA process. Approval to market and distribute these drugs is obtained by filing an abbreviated new drug application (" ANDA ") with the FDA. An ANDA provides for marketing of a drug product that has the same active ingredients in the same strengths and dosage form as the listed drug and has been shown to be bioequivalent to the listed drug. An ANDA is a comprehensive submission that contains, among other things, data and information pertaining to the active pharmaceutical ingredient, drug product formulation, specifications and stability of the generic drug, as well as analytical methods, manufacturing process validation data and quality control procedures. ANDAs are termed abbreviated because they generally do not include preclinical and clinical data to demonstrate safety and effectiveness. Instead, a generic applicant must demonstrate that its product is bioequivalent to **25** the innovator drug. Drugs approved in this way are commonly referred to as " generic equivalents " to the listed drug and can often be substituted by pharmacists under prescriptions written for the original listed drug. Orange Book ListingIn seeking approval for a drug through an NDA, including a 505 (b) (2) NDA, applicants are required to list with the FDA certain patents whose claims cover the applicant' s product. Upon approval, each of the patents listed in the application for the drug is then published in the FDA' s Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Any applicant who files an ANDA seeking approval of a generic equivalent version of a drug listed in the Orange Book or a Section 505 (b) (2) NDA referencing a drug listed in the Orange Book must certify to the FDA, as applicable, that (1) no patent information on the drug product that is the subject of the application has been submitted to the FDA; (2) such patent has expired; (3) the date on which such patent expires; or (4) such patent is invalid or will not be ~~38~~ infringed upon by the manufacture, use or sale of the drug product for which the application is submitted. This last certification is known as a paragraph IV certification. A notice of the paragraph IV certification must be provided to each owner of the patent that is the subject of the certification and to the holder of the approved NDA to which the ANDA or Section 505 (b) (2) application refers. The applicant may also elect to submit a " section viii " statement certifying that its proposed label does not contain (or carves out) any language regarding a patented method- of- use that is approved for the reference drug, rather than certify to a listed method- of- use patent. If within 45 days of receipt of a Paragraph IV Notification the NDA holder for the reference drug and / or patent owners initiates a patent infringement lawsuit against the ANDA or 505 (b) (2) applicant, the FDA is prohibited from approving the application until the earlier of 30 months from the receipt of the paragraph IV certification (the 30- Month Stay), expiration of the patent, settlement

of the lawsuit with a finding of patent invalidity or non- infringement, or a decision in the infringement case that is favorable to the applicant. The ANDA or Section 505 (b) (2) application also will not be approved until any applicable non- patent exclusivity listed in the Orange Book for the reference drug has expired as described in further detail below. Non- Patent ExclusivityIn addition to patent exclusivity, the holder of the NDA for the listed drug may be entitled to a period of non- patent exclusivity, during which the FDA cannot approve an ANDA or Section 505 (b) (2) application that relies on the listed drug. For example, a pharmaceutical manufacturer may obtain five years of non- patent exclusivity upon NDA approval of a new chemical entity, or NCE, which is a drug that contains an active moiety that has not been approved by the FDA in any other NDA. A fixed combination drug product may receive NCE exclusivity if one of its active ingredients is an NCE, but not if all of its active ingredients have previously been approved. An " active moiety " is defined as the molecule or ion responsible for the drug substance' s physiological or pharmacologic action. During the five year exclusivity period, the FDA cannot accept for filing any ANDA seeking approval of a generic version of that drug or any Section 505 (b) (2) NDA for the same active moiety and that relies on the FDA' s findings regarding that drug, except that the FDA may accept such an application for filing after four years if the application includes a paragraph IV certification to a listed patent. In the case of such applications accepted for filing between four and five years after approval of the reference drug, a 30- Month Stay of approval triggered by a timely patent infringement lawsuit is extended by the amount of time necessary to extend the stay until 7- 1 / 2 years after the approval of the reference drug NDA. A drug, including one approved under Section 505 (b) (2), may obtain a three- year period of exclusivity for a particular condition of approval, or change to a marketed product, such as a new formulation for a previously approved product, if one or more new clinical trials (other than bioavailability studies) was essential to the approval of the application and was conducted / sponsored by the applicant. Should this occur, the FDA would be precluded from approving any ANDA or Section 505 (b) (2) application for the protected modification **26** until after that three- year exclusivity period has run. However, unlike NCE exclusivity, the FDA can accept an application and begin the review process during the exclusivity period. Regulation Outside the United StatesTo the extent that any of our product candidates, once approved, are sold in a foreign country, we may be subject to similar foreign laws and regulations, which may include, for instance, applicable post- marketing requirements, including safety surveillance, anti- fraud and abuse laws and implementation of corporate compliance programs and reporting of payments or other transfers of value to healthcare professionals. To market our future products in the EEA (which is comprised of the 27 Member States of the EU plus Norway, Iceland and Liechtenstein) and many other foreign jurisdictions, we must obtain separate regulatory ~~39~~ approvals. More concretely, in the EEA, medicinal products can only be commercialized after obtaining a Marketing Authorization (" MA "). There are two types of marketing authorizations: ● The Community MA, which is issued by the European Commission through the Centralized Procedure, based on the opinion of the Committee for Medicinal Products for Human Use of the European Medicines Agency (" EMA "), and which is valid throughout the entire territory of the EEA. The Centralized Procedure is mandatory for certain types of products, such as biotechnology medicinal products, orphan medicinal products and medicinal products indicated for the treatment of AIDS, cancer, neurodegenerative disorders, diabetes, auto- immune and viral diseases. The Centralized Procedure is optional for products containing a new active substance not yet authorized in the EEA, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the EU; and ● National MAs, which are issued by the competent authorities of the Member States of the EEA and only cover their respective territory, are available for products not falling within the mandatory scope of the Centralized Procedure. Where a product has already been authorized for marketing in a Member State of the EEA, this National MA can be recognized in another Member State through the Mutual Recognition Procedure. If the product has not received a National MA in any Member State at the time of application, it can be approved simultaneously in various Member States through the Decentralized Procedure. Under the above described procedures, before granting the MA, the EMA or the competent authorities of the member countries of the EEA assess the risk-benefit balance of the product based on scientific criteria concerning its quality, safety and efficacy. Data and Marketing ExclusivityIn the EEA, new products authorized for marketing, or reference products, qualify for eight years of data exclusivity and an additional two years of market exclusivity upon marketing authorization. The data exclusivity period prevents generic or biosimilar applicants from relying on the pre- clinical and clinical trial data contained in the dossier of the reference product when applying for a generic or biosimilar marketing authorization in the EU during a period of eight years from the date on which the reference product was first authorized in the EU. The market exclusivity period prevents a successful generic or biosimilar applicant from commercializing its product in the EU until 10 years have elapsed from the initial authorization of the reference product in the EU. The 10- year market exclusivity period can be extended to a maximum of eleven years if, during the first eight years of those 10 years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies. **27** Orphan Drug DesignationIn the EEA, a medicinal product can be designated as an orphan drug if its sponsor can establish that the product is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition affecting not more than five in ten thousand persons in the EU when the application is made, or that the product is intended for the diagnosis, prevention or treatment of a life- threatening, seriously debilitating or serious and chronic condition in the EU and that without incentives it is unlikely that the marketing of the drug in the EU would generate sufficient return to justify the necessary investment in development. For either of these conditions, the applicant must demonstrate that there exists no satisfactory method of diagnosis, prevention or treatment of the condition in question that has been authorized in the EU or, if such method exists, the drug will be of significant benefit to those affected by that condition. In the EEA, an application for designation as an orphan product can be made any time prior to the filing of an application for approval to market the product. Marketing authorization for an orphan drug leads to a ten- year period of market exclusivity. During this market exclusivity period, the EMA or the member state ~~40~~ competent authorities, cannot accept another application for a marketing authorization, or grant a marketing authorization, for a similar medicinal product for the

same indication. The period of market exclusivity is extended by two years for medicines that have also complied with an agreed pediatric investigation plan. This period may, however, be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan drug designation, for example because the product is sufficiently profitable not to justify market exclusivity. Market exclusivity can be revoked only in very selected cases, such as consent from the marketing authorization holder, inability to supply sufficient quantities of the product, demonstration of " clinical superiority " by a similar medicinal product, or, after a review by the Committee for Orphan Medicinal Products, requested by a member state in the fifth year of the marketing exclusivity period (if the designation criteria are believed to no longer apply). Medicinal products designated as orphan drugs are eligible for incentives made available by the EU and its Member States to support research into, and the development and availability of, orphan drugs. Human Capital ResourcesAs of December 31, ~~2022~~ **2023** , we had four full- time employees. Accordingly, a high percentage of our work performed for our development projects is outsourced to qualified independent contractors. All employees and contractors are subject to contractual agreements that specify requirements for confidentiality, ownership of newly developed intellectual property and restrictions on working for competitors as well as other matters. FacilitiesWe do not own or lease any offices at this time other than a " virtual office " at the address set forth on the cover page of this Annual Report. WebsiteOur internet address is https: / / www. virios. com. **28** Item 1A. Risk FactorsAn investment in our securities involves a high degree of risk. You should carefully consider the risks and uncertainties described below and the other information contained in the Annual Report on Form 10- K. Our business, financial condition, results of operations or prospects could be materially and adversely affected if any of these risks occurs, and as a result, the market price of our common stock could decline. Risks Related to Our Financial Position and Need for Additional **CapitalOur recurring losses from operations raise substantial doubt that we will be able to continue as a going concern and our independent registered public accounting firm has issued an audit report that includes an explanatory paragraph referring to the uncertainty regarding our ability to continue as a going concern without additional** ~~CapitalWe~~ -- **capital becoming available. This may hinder our ability to obtain future financing. Our financial statements as of December 31, 2023 were prepared under the assumption that we will continue as a going concern for the next twelve months. Due to our recurring losses from operations, we concluded that there is substantial doubt in our ability to continue as a going concern within one year after the financial statements are issued without additional capital becoming available. Our independent registered public accounting firm has issued an audit report that includes an explanatory paragraph referring to the uncertainty regarding 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. The financial statements do not include any adjustments that might result from the outcome of this uncertainty. We** have incurred losses since inception and anticipate that we will continue to incur losses for the foreseeable future. We are not currently profitable, and we may never achieve or sustain profitability. We are a development- stage biotechnology company with a limited operating history and have incurred losses since our formation. We incurred net losses of $ **5, 296, 015 and $** 12, 247, 834 ~~and $ 15, 960, 268~~ for each of the years ended December 31, **2023 and** 2022 ~~and 2021~~. As of December 31, ~~2022~~ **2023** , we had an accumulated deficit of $ ~~56~~ **61** , ~~173~~ **469** , ~~207~~ **222** . We have not commercialized any products and have never generated revenue from the commercialization of any product. To date, we have devoted most of our financial resources to research and development, including our preclinical and clinical work, and to intellectual property. We expect to incur significant additional operating losses for the next several years, at least, as we advance IMC- 1 **, IMC- 2** and any other **product** candidates through clinical development, complete clinical trials, seek regulatory approval and commercialize the drug or any other **product** candidates, if approved. The costs of advancing **product** candidates into each clinical phase tend to increase substantially over the duration of the clinical development process. Therefore, the total costs to advance any of our **product** candidates to marketing approval in even a single ~~41~~ jurisdiction will be substantial. Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to begin generating revenue from the commercialization of any products or achieve or maintain profitability. Our expenses will also increase substantially if and as we: ● conduct our Phase 3 FM studies or conduct clinical trials for any other indications or other **product** candidates; ● establish sales, marketing, distribution, and compliance infrastructures to commercialize IMC- 1 **or IMC- 2** , if approved, and for any other **product** candidates for which we may obtain marketing approval; ● maintain, expand and protect our intellectual property portfolio; **29** ● hire additional clinical, scientific and commercial personnel; ● add operational, financial and management information systems and personnel, including personnel to support our development and planned future commercialization efforts, as well as to support our transition to a public reporting company; and ● acquire or in- license or invent other **product** candidates or assets. Furthermore, our ability to successfully develop, commercialize and license any **product** candidates and generate product revenue is subject to substantial additional risks and uncertainties, as described below under " — Risks Related to Development, Clinical Testing, Manufacturing and Regulatory Approval " and " — Risks Related to Commercialization. " As a result, we expect to continue to incur net losses and negative cash flows for the foreseeable future. These net losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders' equity and working capital. The amount of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenues. If we are unable to develop and commercialize one or more product candidates, either alone or through collaborations, or if revenues from any product that receives marketing approval are insufficient, we will not achieve profitability. Even if we do achieve profitability, we may not be able to sustain profitability or meet outside expectations for our profitability. If we are unable to achieve or sustain profitability or to meet outside expectations for our profitability, the value of our common stock will be materially and adversely affected. We will require additional capital to fund our operations, and if we fail to obtain necessary financing, we may not be able to complete the development and commercialization of IMC- 1 **or IMC- 2** . Our operations have

consumed substantial amounts of cash since inception. We expect to continue to spend substantial amounts to advance the clinical development , ~~of IMC- 1 and~~ launch and ~~commercialize~~ **commercialization (** ~~IMC- 1,~~ if we receive regulatory approval **) of IMC- 1 and / or IMC- 2** . We will require additional capital for the further development and potential commercialization of IMC- 1 **or** ~~and may also need to raise additional funds sooner to pursue a more accelerated development of~~ IMC- ~~1~~ **2** . If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts. Our cash on hand ~~of $ 7, 030, 992~~ as of December 31, ~~2022~~ **2023** is **not** sufficient to fund our operations and capital requirements for at least the next 12 months subsequent to the filing date of the Company' s Annual Report on Form 10- K. Currently, ~~there~~ -- **the** ~~are no~~ planned research and development activities for ~~2023 other~~ -- **the** ~~than minimal carryover costs~~ **next year include a potential submission of an investigational new drug (" IND ") application to formally access IMC- 2 as a treatment for the symptoms** associated with ~~completing the final reports~~ **LC; purchase of API; continued prototype development of IMC- 2 to be used** for the ~~FORTRESS~~ **Phase 2 LC** study **; continued salaries** and **benefits; and** ~~the chronic toxicology program, regulatory consulting to prepare for the meeting with the FDA, the on- going~~ **ongoing provision of the** grant to **the** BHC ~~for~~ **to execute** ~~the~~ **their** ~~fully funded~~ **double- blinded, placebo controlled** investigator- sponsored study ~~in Long- COVID and purchase~~ of **LC** ~~active pharmaceutical ingredients (" API ") to support the start of a potential Phase 3 study for IMC- 1. We are scheduled to meet~~ with the ~~FDA~~ **combination of Val / Cel which is expected to read out** in ~~March~~ **mid-** ~~2023~~ **2024** ~~to discuss the most appropriate next steps in advancing IMC- 1 development as a 42 treatment for FM~~ . Additional capital will need to be raised before initiating additional research and development activities. We have based this estimate on assumptions that may prove to be wrong, and we could deploy our available capital resources sooner or for other purposes than we currently expect. Our future funding requirements, both near and long- term, will depend on many factors, including, but not limited to the: ● initiation, progress, timing, costs and results of preclinical studies and clinical trials, including patient enrollment in such trials, for IMC- 1 or **IMC- 2 or** any other future **product** candidates; ● clinical development plans we establish for IMC- 1 and **/ or IMC- 2 and** any other future **product** candidates; ● obligation to make royalty and non- royalty sublicense receipt payments to third- party licensors, if any, under our licensing agreements; **30** ● number and characteristics of **product** candidates that we discover or in- license and develop; ● outcome, timing and cost of regulatory review by the FDA and comparable foreign regulatory authorities, including the potential for the FDA or comparable foreign regulatory authorities to require that we perform more studies than those that we currently expect; ● costs of filing, prosecuting, defending and enforcing any patent claims and maintaining and enforcing other intellectual property rights; ● effects of competing technological and market developments; ● costs and timing of the implementation of commercial- scale manufacturing activities; and ● costs and timing of establishing sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval. If we are unable to expand our operations or otherwise capitalize on our business opportunities due to a lack of capital, our ability to become profitable will be compromised. Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates. Until such time, if ever, as we can generate substantial revenue, we may finance our cash needs through a combination of equity offerings, debt financings, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements or other sources. We do not currently have any committed external source of funds. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interests of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our common stockholder' s rights as common stockholders. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights to our technologies, intellectual property, future revenue streams or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate **product** candidate development or future commercialization efforts. ~~43~~ **31** Unstable global market and economic conditions may have serious adverse consequences on our business, financial condition and results of operations. The global economy, including credit and financial markets, has experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates, increases in inflation rates and uncertainty about economic stability. For example, the ~~current~~ **recent Israel- Hamas conflict and ongoing** conflict between Ukraine and Russia has created extreme volatility in the global capital markets and is expected to have further global economic consequences, including disruptions of the global supply chain and energy markets. Any such volatility and disruptions may have adverse consequences on us or the third parties on whom we rely. If the equity and credit markets deteriorate, including as a result of political unrest or war, it may make any necessary debt or equity financing more difficult to obtain in a timely manner or on favorable terms, more costly or more dilutive. We have a limited operating history and no history of commercializing pharmaceutical products, which may make it difficult to evaluate the prospects for our future viability. We were established and began operations in 2012. Our operations to date have been limited to financing and staffing our company, ~~licensing candidates~~ **conducting proof- of- concept studies for IMC- 1 and IMC- 2** , **and** conducting preclinical and clinical studies of IMC- 1. We have further tested IMC- 1 in clinical trials for safety and proof- of- concept. We have not yet demonstrated the ability to successfully complete a large- scale, pivotal clinical trial, obtain marketing approval, manufacture a commercial scale product, arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Consequently, predictions about our future success or viability may not be as accurate as they could be if we had a history of successfully developing and commercializing

pharmaceutical products. In addition, as a business with a limited operating history, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. We will eventually need to transition from a company with a research focus to a company capable of supporting commercial activities. We may not be successful in such a transition and, as a result, our business may be adversely affected. As we continue to build our business, we expect our financial condition and operating results may fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. Accordingly, the results of any particular quarterly or annual period should not be relied upon as indications of future operating performance. Risks Related to Development, Clinical Testing, Manufacturing and Regulatory ApprovalWe are heavily dependent on the success of **our product candidates,** IMC- 1 ~~, our lead candidate~~ **and IMC- 2** , which ~~is~~ **are** still under clinical development, and if ~~this~~ **these** ~~candidate~~ **candidates** ~~does~~ **do** not receive regulatory approval or, if approved, our commercialization efforts are unsuccessful, our business may be harmed. We do not have any products that have been granted regulatory approval. Currently, **we have two product** ~~our lead development- stage candidate~~ **candidates** ~~is ,~~ IMC- 1 **and IMC- 2** . As a result, our business is dependent on our ability to successfully complete clinical development of, obtain regulatory approval for, and, if approved, successfully commercialize IMC- 1 **and / or IMC- 2** in a timely manner. We cannot commercialize IMC- 1 **or IMC- 2** in the United States without first obtaining regulatory approval from the FDA; similarly, we cannot commercialize IMC- 1 **or IMC- 2** outside of the United States without obtaining regulatory approval from comparable foreign regulatory authorities. Before obtaining regulatory approvals for the commercial sale of IMC- 1 **or IMC- 2** for a target indication, we must demonstrate with substantial evidence gathered in preclinical studies and clinical trials and, with respect to approval in the United States, to the satisfaction of the FDA, that IMC- 1 **or IMC- 2** is safe and effective for use for that target indication and that the manufacturing facilities, processes and controls are adequate. In our most recent clinical trial involving IMC- 1, the Phase 2b FORTRESS study, IMC- 1 did not achieve statistically significant efficacy outcomes. Even if IMC- 1 were to successfully obtain approval from the **32** FDA and comparable foreign regulatory authorities, any approval might contain significant limitations related to use restrictions for specified ~~44~~ age groups, warnings, precautions or contraindications, or may be subject to burdensome post- approval study or risk management requirements. If we are unable to obtain regulatory approval for IMC- 1 in one or more jurisdictions, or any approval we receive contains significant limitations or requirements, we may not be able to obtain sufficient funding or generate sufficient revenue to continue the development of any other **product** candidate that we may in- license, develop or acquire in the future. Furthermore, even if we obtain regulatory approval for IMC- 1, we will still need to develop a commercial organization, establish commercially viable pricing and obtain approval for adequate reimbursement from third- party and government payors. If we are unable to successfully commercialize IMC- 1 **or IMC- 2** , we may not be able to earn sufficient revenue to continue our business. We may face future business disruption and related risks resulting from the spread of infectious disease, ~~including coronavirus 2019 variants (COVID- 19),~~ which could have a material adverse effect on our business. The development of our ~~drug~~ **product** candidates could be disrupted and materially adversely affected in the future by a pandemic, epidemic or outbreak of an infectious disease. The spread of an infectious disease ~~, including COVID- 19,~~ may also result in the inability of our suppliers to deliver components or raw materials on a timely basis or materially and adversely affect our collaborators and out- license partners' ability to perform preclinical studies and clinical trials. In addition, hospitals may reduce staffing and reduce or postpone certain treatments in response to the spread of an infectious disease. Such events may result in a period of business and manufacturing disruption, and in reduced operations, any of which could materially affect our business, financial condition and results of operations. The ultimate extent of the impact of any epidemic, pandemic or other health crisis ~~, including COVID- 19,~~ on our ability to advance the development of our ~~drug~~ **product** candidates, including delays in starting or completing clinical trials, or to raise financing to support the development of our ~~drug~~ **product** candidates, will depend on future developments, which are highly uncertain and cannot be accurately predicted, including new information that may emerge concerning the severity of such epidemic, pandemic or other health crisis and actions taken to contain or prevent their further spread, among others. Clinical trials are expensive, time- consuming and difficult to design and implement ~~,~~ and involve an uncertain outcome. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. Because the results of preclinical studies and early clinical trials are not necessarily predictive of future results, IMC- 1 **, IMC- 2** and our other compounds may not have favorable results in later preclinical and clinical studies or receive regulatory approval. We may experience delays in initiating and completing any clinical trials that we intend to conduct, and we do not know whether planned clinical trials will begin on time, need to be redesigned, enroll patients on time or be completed on schedule, or at all. Clinical trials can be delayed for a variety of reasons, including delays related to: ● the FDA or comparable foreign regulatory authorities disagreeing as to the design or implementation of our clinical studies; ● obtaining regulatory approval to commence a trial; ● reaching an agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites; ● obtaining Institutional Review Board, or IRB, approval at each site, or Independent Ethics Committee, or IEC, approval at sites outside the United States; ~~45~~ **33** ● recruiting suitable patients to participate in a trial in a timely manner and in sufficient numbers; ● having patients complete a trial or return for post- treatment follow- up; ● imposition of a clinical hold by regulatory authorities or IRBs, including as a result of unforeseen safety issues or side effects or failure of trial sites to adhere to regulatory requirements or follow trial protocols; ● clinical sites deviating from trial protocol, committing fraud or other violations of regulatory requirements, or dropping out of a trial, which can render data from that site unusable in support of regulatory approval; ● addressing patient safety concerns that arise during the course of a trial; ● adding a sufficient number of clinical trial sites; or ● manufacturing sufficient quantities of IMC- 1 **or IMC- 2** for use in clinical trials. We could also encounter delays if a clinical trial is suspended or terminated by us, the IRBs or IECs of the institutions in which such trials are being conducted, the Data Safety Monitoring Board, or DSMB, for such trial or the FDA or other regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to

conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. Furthermore, we rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials and, while we have agreements governing their committed activities, we have limited influence over their actual performance, as described in " Risks Related to Our Dependence on Third Parties. " The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming, expensive, and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for IMC- 1 **, IMC- 2** or any other **product** candidates, our business will be substantially harmed. The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a **product** candidate' s clinical development and may vary among jurisdictions. We have not obtained regulatory approval for any product candidate and it is possible that we will never obtain regulatory approval for IMC- 1 **, IMC- 2** or any other **product** candidates. We are not permitted to market any of our product candidates in the United States until we receive regulatory approval from the FDA. **Our ability to successfully obtain regulatory approval from the FDA or comparable foreign regulatory authorities is subject to many risks and uncertainties, including the occurrence of one or more of the following:** ● we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a **product** candidate is safe and effective for its proposed indication; ● serious and unexpected treatment- related side effects experienced by participants in our clinical trials or by individuals using drugs similar to our **product** candidates, or other products containing the active ingredient in our **product** candidates; **34** ● negative or ambiguous results from our clinical trials or results that may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval; ~~46~~ ● we may be unable to demonstrate that a **product** candidate' s clinical and other benefits outweigh its safety risks; ● the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials; ● the data collected from clinical trials of our ~~development~~ **product** candidates may not be acceptable or sufficient to support the submission of an NDA or other submission or to obtain regulatory approval in the United States or elsewhere, and we may be required to conduct additional clinical trials; ● the FDA or comparable foreign authorities may disagree regarding the formulation, labeling and / or the specifications of our **product** candidates; ● the FDA or comparable foreign regulatory authorities may fail to approve or find deficiencies with the manufacturing processes or facilities of third- party manufacturers with which we contract for clinical and commercial supplies; ● the FDA or comparable foreign regulatory authorities may inspect and find deficiencies at the clinical trial sites we use to conduct our clinical studies; and ● the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval. Prior to obtaining approval to commercialize a **product** candidate in the United States or ~~abroad~~ **in a foreign jurisdiction** , we must demonstrate with substantial evidence from well- controlled clinical trials, and to the satisfaction of the FDA or **comparable** foreign regulatory agencies, that such **product** candidates are safe and effective for their intended uses. Results from preclinical studies and clinical trials can be interpreted in different ways. Even if we believe the preclinical or clinical data for our **product** candidates are promising, such data may not be sufficient to support approval by the FDA and other regulatory authorities. The FDA or ~~any~~ **comparable** foreign regulatory bodies can delay, limit or deny approval of our **product** candidates or require us to conduct additional preclinical or clinical testing or abandon a program for many reasons, including: ● the FDA or comparable foreign regulatory authorities may disagree with the adequacy of the design or implementation of our clinical trials; ● the FDA or comparable foreign regulatory authorities may disagree with our safety interpretation of our drug; ● the FDA or comparable foreign regulatory authorities may disagree with our efficacy interpretation of our drug; or ● the FDA or comparable foreign regulatory authorities may regard our CMC package as inadequate, and more particularly: ● if our NDA does not include adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof; **35** ● if the results of such tests show that such drug is unsafe for use under such conditions or do not show that such drug is safe for use under such conditions; ~~47~~ ● if the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to preserve its identity, strength, quality, and purity; ● if FDA determines that it has insufficient information to determine whether such drug is safe for use under such conditions; ● if based on information we submit and any other information before the FDA, the FDA determines there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof; or ● if FDA determines that our labeling is false or misleading in any particular way. Of the large number of drugs in development, only a small percentage successfully complete the regulatory approval processes and are commercialized. This lengthy approval process, as well as the unpredictability of future clinical trial results, may result in our failing to obtain regulatory approval to market IMC- 1 **, IMC- 2** or another **product** candidate, which would significantly harm our business, results of operations and prospects. In addition, the FDA or the applicable **comparable** foreign regulatory agency also may approve a product candidate for a more limited indication or patient population than we originally requested, the FDA or applicable foreign regulatory agency may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate, or may require warnings, other safety- related labeling information, or impose post- market safety requirements, including distribution restrictions, that negatively impact the commercial potential of the drug. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates. Enrollment and retention of patients in clinical trials is an expensive and time- consuming process and could be made more difficult or rendered impossible by multiple factors outside our control. The timely completion of clinical

trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the study until its conclusion. We may encounter delays in enrolling, or be unable to enroll, a sufficient number of patients to complete any of our clinical trials, and even once enrolled, we may be unable to retain a sufficient number of patients to complete any of our trials. Patient enrollment and retention in clinical trials depends on many factors, including: ● the patient eligibility criteria defined in the protocol; ● the size of the patient population required for analysis of the trial' s primary endpoints; ● the nature of the trial protocol; ● the existing body of safety and efficacy data with respect to the product candidate; ● the proximity of patients to clinical sites; ● our ability to recruit clinical trial investigators with the appropriate competencies and experience; **36** ● clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating; ● competing clinical trials being conducted by other companies or institutions; ~~48~~ ● our ability to maintain patient consents; and ● the risk that patients enrolled in clinical trials will drop out of the trials before completion. Results of preclinical studies, early clinical trials or analyses may not be indicative of results obtained in later trials. The results of preclinical studies, early clinical trials or analyses of our product candidates may not be predictive of the results of later- stage clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. In addition, conclusions based on promising data from analyses of clinical results may be shown to be incorrect when implemented in prospective clinical trials. Even if our clinical trials for IMC- 1 **and IMC- 2** are completed as planned, we cannot be certain that their results will support the safety and efficacy sufficient to obtain regulatory approval. From time to time, we may publish interim " top- line " or preliminary data from our clinical studies. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Preliminary or " top- line " data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim and preliminary data should be viewed with caution until the final data are available. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects. Serious adverse events or undesirable side effects caused by IMC- 1 **, IMC- 2** or any other **product** candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign authorities. Results of any clinical trial we conduct could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. Patients treated with IMC- 1 in our Phase 2a and Phase 2b studies discontinued **their participation** due to adverse events at a rate lower than patients treated with placebo. The most common adverse events IMC- 1 patients experienced (other than COVID- 19 infection) were gastrointestinal events and headache at rates less than 5 %. There were three serious adverse events observed in the Phase 2a study, two on patients treated with IMC- 1, and one for a placebo treated patient. In the larger Phase 2b study, there were three serious adverse events that occurred in two patients, both of whom were treated with placebo. If unacceptable side effects arise in the development of our **product** candidates, we, the FDA or the IRBs at the institutions in which our studies are conducted, or the DSMB, if constituted for our clinical trials, could recommend a suspension or termination of our clinical trials, or the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of a product candidate for any or all targeted indications. In addition, drug- related side effects could affect patient recruitment or the ability of enrolled patients to complete a trial or result in potential product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff. We expect to have to train medical personnel using our ~~development~~ **product** candidates to understand the side effect profiles for our clinical trials and upon any commercialization of any of our product candidates. Inadequate training in recognizing or managing the potential side effects of our product candidates could result in patient injury or death. Any of these occurrences may harm our business, financial condition and prospects significantly. **37** Additionally, if one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects caused by such products, a number of potentially significant negative consequences could result, including: ● regulatory authorities may withdraw approvals of such product; ~~49~~ ● regulatory authorities may require additional warnings on the label, such as a " black box " warning or contraindication; ● additional restrictions may be imposed on the marketing of the particular product or the manufacturing processes for the product or any component thereof; ● we may be required to implement a Risk Evaluation and Mitigation Strategy, or REMS, or create a medication guide outlining the risks of such side effects for distribution to patients; ● we could be sued and held liable for harm caused to patients; ● the product may become less competitive; and ● our reputation may suffer. Any of these events could prevent us from achieving or maintaining market acceptance of a product candidate, if approved, and could significantly harm our business, results of operations and prospects. The market opportunities for IMC- 1 **or IMC- 2** , if approved, may be smaller than we anticipate. We **are developing** ~~expect to initially seek approval for~~ IMC- 1 for **the treatment of** FM ~~in~~ **and IMC- 2 for** the ~~United States~~ **treatment of LC** . Our estimates of market potential have been derived from a variety of sources, including scientific literature, patient foundations and primary and secondary market research, and may prove to be incorrect. Even if we obtain significant market share for any product candidate, if approved, if the potential target populations are small, we may never achieve profitability without obtaining marketing approval for additional indications. We have never obtained marketing approval for a ~~development~~ **product** candidate and we may be unable to obtain, or may be delayed in obtaining, marketing approval for any of our ~~development~~ **product** candidates. We have never obtained marketing approval for a product candidate. It is possible that the FDA may refuse to accept for substantive review any NDAs that we submit for our ~~development~~ **product** candidates or may conclude after review of our data that our application is insufficient to obtain marketing approval of our ~~development~~ **product** candidates. If the FDA does not accept or approve our NDAs for our ~~development~~ **product** candidates, it may require that we

conduct additional clinical, preclinical or manufacturing validation studies and submit that data before it will reconsider our applications. Depending on the extent of these or any other FDA- required studies, approval of any NDA that we submit may be delayed or may require us to expend more resources than we have available. It is also possible that additional studies, if performed and completed, may not be considered sufficient by the FDA to approve our NDAs. Any delay in obtaining, or an inability to obtain, marketing approvals would prevent us from commercializing our ~~development~~ **product** candidates, generating revenues and achieving and sustaining profitability. If any of these outcomes occur, we may be forced to abandon our development efforts for our product candidates, which could significantly harm our business. **38** Even if we obtain FDA approval for IMC- 1 **, IMC- 2** or any other **product** candidates in the United States, we may never obtain approval for or commercialize IMC- 1 **, IMC- 2** or any other ~~development~~ **product** candidate in any other jurisdiction, which would limit our ability to realize their full global market potential. In order to market any products in any particular jurisdiction, we must establish and comply with numerous and varying regulatory requirements on a country- by- country basis regarding safety and efficacy. Approval by the FDA in the United States does not ensure approval by regulatory authorities in other ~~countries or~~ jurisdictions. However, the failure to obtain approval in one jurisdiction may negatively impact our ability to obtain approval elsewhere. In addition, clinical trials conducted in one country may not be accepted ~~50~~ by regulatory authorities in other countries, and regulatory approval in one country does not guarantee regulatory approval in any other country. Approval processes vary ~~among countries~~ **between jurisdictions** and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approval could result in difficulties and increased costs for us and require additional preclinical studies or clinical trials which could be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. We do not have any product candidates approved for sale in any jurisdiction, including in international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approvals in international markets are delayed, our target market will be reduced and our ability to realize the full market potential of any product we develop will be unrealized. Even if we obtain regulatory approval for IMC- 1 **, IMC- 2** or any ~~development~~ **other product** candidate, we will still face extensive and ongoing regulatory requirements and obligations and any ~~development~~ **product** candidates, if approved, may face future development and regulatory difficulties. Any **product** candidate for which we obtain marketing approval, along with the manufacturing processes, post- approval clinical data, labeling, packaging, distribution, adverse event reporting, storage, recordkeeping, export, import, advertising and promotional activities for such product, among other things, will be subject to extensive and ongoing requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety and other post- marketing information and reports, establishment registration and drug listing requirements, continued compliance with current Good Manufacturing Practice, or cGMP, requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping and Good Clinical Practice, or GCP, requirements for any clinical trials that we conduct post- approval. Even if marketing approval of a product candidate is granted, the approval may be subject to limitations on the indicated uses for which the product candidate may be marketed or to the conditions of approval, including a requirement to implement a REMS. If any of our product candidates receive marketing approval, the accompanying label may limit the approved indicated use of the product candidate, which could limit sales of the product candidate. The FDA may also impose requirements for costly post- marketing studies or clinical trials and surveillance to monitor the safety or efficacy of a product. The FDA closely regulates the post- approval marketing and promotion of drugs to ensure drugs are marketed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding off- label use, and if we market our products for uses beyond their approved indications, we may be subject to enforcement action for off- label marketing. Violations of the Federal Food, Drug, and Cosmetic Act, or FDCA, relating to the promotion of prescription drugs may lead to FDA enforcement actions and investigations alleging violations of federal and state healthcare fraud and abuse laws, as well as state consumer protection laws. **39** In addition, later discovery of previously unknown adverse events or other problems with our products, manufacturers or manufacturing processes or failure to comply with regulatory requirements, may yield various results, including: ● restrictions on manufacturing such products; ● restrictions on the labeling or marketing of products; ● restrictions on product distribution or use; ● requirements to conduct post- marketing studies or clinical trials; ~~51~~ ● warning letters or untitled letters; ● withdrawal of the products from the market; ● refusal to approve pending applications or supplements to approved applications that we submit; ● recall of products; ● fines, restitution or disgorgement of profits or revenues; ● suspension or withdrawal of marketing approvals; ● refusal to permit the import or export of our products; ● product seizure; or ● injunctions or the imposition of civil or criminal penalties. Further, the FDA' s policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, which would adversely affect our business, prospects and ability to achieve or sustain profitability. We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or ~~abroad~~ **in foreign jurisdictions** . For example, certain policies of the current presidential administration may impact our business and industry. Namely, the current presidential administration has taken several executive actions, including the issuance of a number of executive orders, which could impose significant burdens on, or otherwise materially delay, the FDA' s ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. It is difficult to predict how these executive actions will be implemented, and the extent to which they will impact the FDA' s ability to exercise its regulatory authority. If these executive actions impose constraints on

FDA' s ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted. We may seek a Breakthrough Therapy designation for IMC- 1 **or IMC- 2** from the FDA. However, we might not receive such designation, and even if we do, such designation may not lead to a faster development or regulatory review or approval process. We may seek a Breakthrough Therapy designation for IMC- 1 **, IMC- 2** or one or more of our other **product** candidates. A Breakthrough Therapy is defined as a drug that is intended, alone or in combination with one or **40** more other drugs, to treat a serious condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For drugs that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Drugs designated as breakthrough therapies by the FDA may also be eligible for priority review if supported by clinical data at the time the NDA is submitted to the FDA. Designation as a Breakthrough Therapy is within the discretion of the FDA. Accordingly, even if we believe that one of our **product** candidates meets the criteria for designation as a Breakthrough Therapy, the FDA may disagree and instead determine not to make such designation. Even if we receive Breakthrough Therapy designation, the receipt of such designation for a product candidate may not result in a faster development or ~~52~~ regulatory review or approval process compared to drugs considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify as breakthrough therapies, the FDA may later decide that the product candidates no longer meet the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. Potential product liability lawsuits against us could cause us to incur substantial liabilities and limit commercialization of any products that we may develop. The use of IMC- 1 **, IMC- 2** or any other **product** candidates we may develop in clinical trials and the sale of any products for which we obtain marketing approval exposes us to the risk of product liability claims. Product liability claims might be brought against us by patients, healthcare providers, pharmaceutical companies or others selling or otherwise coming into contact with our products. On occasion, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated adverse effects. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs. In addition, regardless of merit or eventual outcome, product liability claims may result in: ● impairment of our business reputation and significant negative media attention; ● withdrawal of participants from our clinical trials; ● significant costs to defend the litigation; ● distraction of management' s attention from our primary business; ● substantial monetary awards to patients or other claimants; ● inability to commercialize IMC- 1 **, IMC- 2** or any other product candidate; ● product recalls, withdrawals or labeling, marketing or promotional restrictions; ● decreased market demand for any product; and ● loss of revenue. The product liability insurance coverage we plan to acquire in the future may not be sufficient to reimburse us for any expenses or losses we may suffer. In connection with our Phase 1 clinical studies, we carried insurance for product liability claims in the United States. We intend to acquire insurance coverage to include larger clinical studies, different countries and sale of commercial products; however, we may be unable to obtain product liability insurance on commercially reasonable terms or in adequate amounts. **41** A successful product liability claim, or series of claims, brought against us could cause our share price to decline and, if judgments exceed our insurance coverage, could adversely affect the results of our operations and business, including preventing or limiting the commercialization of any product candidates we develop. Risks Related to CommercializationWe face significant competition from other biotechnology and pharmaceutical companies and our operating results will suffer if we fail to compete effectively. The biopharmaceutical and pharmaceutical industries are highly competitive and subject to significant and rapid technological change. Our success is highly dependent on our ability to acquire, develop, and obtain marketing approval for new products on a cost- effective basis and to market them successfully. If ~~53~~ **either or both of** IMC- 1 **or IMC- 2** is approved, we will face intense competition from a variety of businesses, including large, fully integrated pharmaceutical companies, specialty pharmaceutical companies and biopharmaceutical companies in the United States and other jurisdictions. These organizations may have significantly greater resources than we do and may conduct similar research; seek patent protection; and establish collaborative arrangements for research, development, manufacturing and marketing of products that may compete with us. Our competitors may, among other things: ● have significantly greater name recognition, financial, manufacturing, marketing, drug development, technical, and human resources than we do, and future mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors; ● develop and commercialize products that are safer, more effective, less expensive, more convenient, or easier to administer, or have fewer or less severe effects; ● obtain quicker regulatory approval; ● implement more effective approaches to sales and marketing; or ● form more advantageous strategic alliances. Smaller and other early- stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel; establishing clinical trial sites and patient registration; and in acquiring technologies complementary to, or necessary for, our programs. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are more effective, have fewer or less severe side effects, or are more convenient or are less expensive ~~than IMC- 1~~. Our competitors may also obtain FDA or other regulatory approval for their product candidates more rapidly than we may obtain approval for **ours** ~~IMC- 1~~, which could result in our competitors establishing or strengthening their market position before we are able to enter the market. We may face early generic competition for IMC- 1 ~~or~~ **, IMC- 2** ~~our~~ **or any** other products **we successfully develop and market** . Pharmaceutical companies developing novel products face intense competition from generic drug manufacturers who aggressively seek to challenge patents and non- patent exclusivities for branded products, and who are able to use much less- onerous product development and FDA approval pathways for their generic products. Both of the active ingredients of IMC- 1, famciclovir and celecoxib, **and IMC- 2, valacyclovir and celecoxib,** are marketed in numerous FDA- approved single- ingredient generic

products that copy the **42** original brand name products containing those active ingredients, indicating that numerous potential generic competitors have successfully developed formulation and manufacturing processes to make finished drug products of the individual components of IMC- 1 **and IMC- 2** using these ingredients. Such generic competitors could apply those processes to develop equivalent generic versions of IMC- 1 **or IMC- 2** . Under FDA' s generic drug approval processes, described in more detail in the section titled " Hatch- Waxman and Generic Competition, " we do not believe that **either** IMC- 1 **or IMC- 2** would be eligible for the 5- year NCE Exclusivity period, because both active ingredients have previously been approved by FDA in other branded drug products, although ~~ICM~~ **either or both of IMC** - 1 **or IMC- 2** may qualify for a 3- year exclusivity period during which no generic version could be approved. As discussed elsewhere herein, we have procured several patents that we believe cover IMC- 1 and would be eligible for listing in FDA' s Orange Book, and as such would require any proposed generic competitor to IMC- 1 **or IMC- 2** seeking FDA approval prior to the expiration of such patents to submit a Paragraph IV Certification alleging that our patent (s) are invalid, unenforceable, or would not be infringed by the marketing of the proposed generic product. Such a Paragraph IV ANDA could be submitted to **the** FDA at any time after approval of the IMC- 1 **or IMC- 2** NDA, but if we file a patent infringement action against such a generic challenger within 45 days of receiving the required notification of such Paragraph IV ~~54~~ filing, FDA would be barred from approving the generic version for **typically** 30 months from the date of our receipt of the notification. This 30- Month Stay, however, may be shortened if the court earlier decides that our patents are in fact invalid, unenforceable, or would not be infringed. Even if the litigation is not concluded at the end of the 30- Month Stay, FDA may still grant final approval of the generic application, and the applicant would be able to choose to launch its product, absent a court- ordered injunction, but at the risk of becoming liable to us for monetary infringement damages, including potentially treble damages, if we ultimately prevail in the litigation. IMC- 1 uses novel dosage strengths of both famciclovir **and celecoxib, and IMC- 2 uses novel dosage strengths of valacyclovir** and celecoxib, neither of which dosage strengths have been approved by FDA for other products. Thus, there are no currently ~~-~~ approved single- ingredient generic products that could readily be prescribed in combination as a direct equivalent substitute for IMC- 1 **or IMC- 2** . However, physicians are lawfully able to prescribe drugs for unapproved uses and in unapproved strengths, and it is possible that some physicians could seek to prescribe separately approved generic versions of these ~~two~~ drugs in combination as a treatment for FM **, LC** or other proposed indications for IMC- 1 **or IMC- 2** , in an attempt to lower the costs to their patients. The successful commercialization of IMC- 1 **, IMC- 2** and any other **product** candidate we develop will depend in part on the extent to which governmental authorities and health insurers establish adequate coverage, reimbursement levels, and pricing policies. Failure to obtain or maintain coverage and adequate reimbursement for our **product** candidates, if approved, could limit our ability to market those products and decrease our ability to generate revenue. The availability and adequacy of coverage and reimbursement by governmental healthcare programs such as Medicare and Medicaid, private health insurers and other third- party payors are essential for most patients to be able to afford prescription medications such as IMC- 1 **or IMC- 2** , if approved. Our ability to achieve acceptable levels of coverage and reimbursement for products by governmental authorities, private health insurers and other organizations will have an effect on our ability to successfully commercialize our drug and any other product candidates we develop. Assuming we obtain coverage for our product candidates by a third- party payor, the resulting reimbursement payment rates may not be adequate or may require co- payments that patients find unacceptably high. We cannot be sure that coverage and reimbursement in the United States or elsewhere will be available for our product candidates or any product that we may develop, and any reimbursement that may become available may be decreased or eliminated in the future. Third- party payors increasingly are challenging prices charged for pharmaceutical products and services, and many third- party payors may refuse to provide coverage and reimbursement for particular drugs or biologics when an equivalent generic drug, biosimilar, or a less expensive therapy is available. It is possible that a third- party payor may consider our product candidates as substitutable and offer to reimburse patients only for the less expensive product. Even if we show improved efficacy or improved convenience of **43** administration with our product candidates, pricing of existing drugs may limit the amount we will be able to charge for our product candidates. These payors may deny or revoke the reimbursement status of a given product or establish prices for new or existing marketed products at levels that are too low to enable us to realize an appropriate return on our investment in our product candidates. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our product candidates and may not be able to obtain a satisfactory financial return on our product candidates. There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In the United States, third- party payors, including private and governmental payors, such as the Medicare and Medicaid programs, play an important role in determining the extent to which new drugs and biologics will be covered. The Medicare and Medicaid programs increasingly are used as models in the United States for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs and biologics. Some third- party payors may require pre- approval of coverage for new or innovative devices or drug therapies before they will reimburse healthcare providers who use such therapies. It is difficult to predict at this time what third- party payors will decide with respect to the coverage and reimbursement for our product candidates. ~~55~~ No uniform policy for coverage and reimbursement for products exists among third- party payors in the United States. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time- consuming and costly process that will require us to provide scientific and clinical support for the use of our product candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Furthermore, rules and regulations regarding reimbursement change frequently, in some cases at short notice, and we believe that changes in these rules and regulations are likely. We may also be subject to extensive governmental price controls and other market regulations outside of the United States, and we believe the increasing emphasis on cost- containment initiatives in other countries have and will continue to put pressure on the pricing and usage of medical products. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems.

Other countries allow companies to fix their own prices for medical products but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the United States, the reimbursement for our product candidates may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits. Moreover, increasing efforts by governmental and third- party payors in the United States to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our product candidates. We expect to experience pricing pressures in connection with the sale of our product candidates due to the trend toward managed health care, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and biologics and surgical procedures and other treatments, has become intense. As a result, increasingly high barriers are being erected to the entry of new products. Even if IMC- 1 **, IMC- 2** or any other **product** candidate we develop receives marketing approval, it may fail to achieve market acceptance by physicians, patients, third- party payors or others in the medical community necessary for commercial success. If IMC- 1 **, IMC- 2** or any other **product** candidate we develop receives marketing approval, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third- party payors and others in the medical community. If it does not achieve an adequate level of acceptance, we may not generate **44** significant product revenues or become profitable. The degree of market acceptance of our product candidates, if approved, will depend on a number of factors, including but not limited to: ● the efficacy and potential advantages compared to alternative treatments; ● effectiveness of our sales and marketing efforts; ● the cost of treatment in relation to alternative treatments, including any similar generic treatments; ● our ability to offer our products for sale at competitive prices; ● the convenience and ease of administration compared to alternative treatments; ● the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies; ● the strength of marketing and distribution support; ~~56~~ ● the availability of third- party coverage and adequate reimbursement; ● the prevalence and severity of any side effects; and ● the impact of any restrictions on the use of our product together with other medications. Because we expect sales of our product candidates, if approved, to generate substantially all of our revenues for the foreseeable future, the failure of our product candidates to find market acceptance would harm our business and could require us to seek additional financing. If we are unable to establish sales, marketing and distribution capabilities either on our own or in collaboration with third parties, we may not be successful in commercializing IMC- 1 **or IMC- 2** , if approved. We do not have any infrastructure for the sales, marketing or distribution of IMC- 1 **or IMC- 2** , or compliance functions related to such activities, and the cost of establishing and maintaining such an organization may exceed the cost- effectiveness of doing so. In order to market and successfully commercialize ~~our drug or~~ any **of our** product ~~candidate~~ **candidates that receive regulatory** ~~we develop, if approved~~ **approval** , we must build our sales, distribution, marketing, managerial, compliance, and other non- technical capabilities or make arrangements with third parties to perform these services. We expect to build a focused sales, distribution and marketing infrastructure to market IMC- 1 **and / or IMC- 2** , if approved, in the United States and ~~Europe~~ **potential other major markets** . There are significant expenses and risks involved with establishing our own sales, marketing and distribution capabilities, including our ability to hire, retain and appropriately incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel, oversee the compliance of sales and marketing functions, and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing, distribution and compliance capabilities could delay any product launch, which would adversely impact the commercialization of that product. For example, if the commercial launch of IMC- 1 **and / or IMC- 2** for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel. Factors that may inhibit our efforts to commercialize our product candidates on our own include: ● our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel; **45** ● the inability of sales personnel to obtain access to physicians or attain adequate numbers of physicians to prescribe our products; and ● unforeseen costs and expenses associated with creating an independent sales and marketing organization. We do not anticipate having the resources in the foreseeable future to allocate to the sales and marketing of our product candidates, if approved, in certain markets overseas. Therefore, our future success will depend, in part, on our ability to enter into and maintain collaborative relationships for such capabilities, the collaborator' s strategic interest in a product and such collaborator' s ability to successfully market and sell the product. We intend to pursue collaborative arrangements regarding the sale and marketing of ~~IMC- 1~~ **our product candidates** , if approved, for certain markets overseas; however, there can be no assurance that we will be able to establish or maintain such collaborative arrangements, or if able to do so, that they will have effective sales forces. To the extent that we depend on third parties for marketing and distribution, any revenues we receive will depend upon the efforts of such third parties, and there can be no assurance that such efforts will be successful. If we are unable to build our own sales force or negotiate a collaborative relationship for the commercialization of IMC- 1 **and / or IMC- 2** , we may be forced to delay the potential commercialization of the drug or reduce ~~57~~ the scope of our sales or marketing activities. If we need to increase our expenditures to fund commercialization activities for IMC- 1 **and / or IMC- 2** we will need to obtain additional capital, which may not be available to us on acceptable terms, or at all. We may also have to enter into collaborative arrangements for IMC- 1 **or IMC- 2** at an earlier stage than otherwise would be ideal and we may be required to relinquish rights to it or otherwise agree to terms unfavorable to us. Any of these occurrences may have an adverse effect on our business, operating results and prospects. If we are unable to establish adequate sales, marketing and distribution capabilities, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates and may never become profitable. We will be competing with many companies that currently have extensive and well- funded marketing and sales operations. Without an internal team or the support of a third party to perform marketing and

sales functions, we may be unable to compete successfully against these more established companies. A variety of risks associated with operating internationally could materially adversely affect our business. We currently have no international operations, but our business strategy includes potentially expanding internationally if any of our product candidates receive regulatory approval. Doing business internationally involves a number of risks, including but not limited to: ● difficulties maintaining compliance with multiple, conflicting and changing laws and regulations, such as privacy regulations, tax laws, export and import restrictions, employment laws, regulatory requirements and other governmental approvals, permits and licenses; ● failure by us to obtain and maintain regulatory approvals for the use of our products in various countries; ● additional potentially relevant third- party patent rights; ● complexities and difficulties in obtaining protection and enforcing our intellectual property; ● difficulties in staffing and managing foreign operations; **46** ● complexities associated with managing multiple payor reimbursement regimes, government payors or patient self- pay systems; ● limits in our ability to penetrate international markets; ● financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the impact of local and regional financial crises on demand and payment for our products and exposure to foreign currency exchange rate fluctuations; ● natural disasters, political and economic instability, including wars, terrorism and political unrest, outbreak of disease, boycotts, curtailment of trade and other business restrictions; ● certain expenses including, among others, expenses for travel, translation and insurance; and ● regulatory and compliance risks that relate to maintaining accurate information and control over sales and activities that may fall within the purview of the U. S. Foreign Corrupt Practices Act, its books and records provisions, or its anti- bribery provisions. ~~58~~ Any of these factors could significantly harm any future international expansion and operations and, consequently, our results of operations. Risks Related to Our Dependence on Third PartiesOur employees and independent contractors, including principal investigators, clinical trial sites, CROs, consultants, vendors, and any third parties we may engage in connection with development and commercialization, may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have a material adverse effect on our business. Our employees and independent contractors, including principal investigators, clinical trial sites, consultants, vendors and any third parties we may engage in connection with development and commercialization of our product candidates, could engage in misconduct, including intentional, reckless or negligent conduct or unauthorized activities that violate: the laws and regulations of the FDA or other similar regulatory requirements of other authorities, including those laws that require the reporting of true, complete and accurate information to such authorities; manufacturing standards; data privacy, security, fraud and abuse and other healthcare laws and regulations; or laws that require the reporting of true, complete and accurate financial information and data. Specifically, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self- dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Activities subject to these laws could also involve the improper use or misrepresentation of information obtained in the course of clinical trials, creation of fraudulent data in preclinical studies or clinical trials or illegal misappropriation of drug product, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with such laws or regulations. Additionally, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgements, possible exclusion from participation in Medicare, Medicaid, other U. S. federal healthcare programs or healthcare programs in other jurisdictions, individual imprisonment, other **47** sanctions, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations. We currently rely on third- party contract manufacturing organizations, or CMOs, for the production of clinical supply of IMC- 1 and **IMC- 2 and** intend to rely on CMOs for the production of commercial supply of IMC- 1 **and IMC- 2** , if approved. Our dependence on CMOs may impair the development and commercialization of the drug, which would adversely impact our business and financial position. We have limited personnel with experience in manufacturing, and we do not own facilities for manufacturing. Instead, we rely on and expect to continue to rely on CMOs for the supply of cGMP grade clinical trial materials and commercial quantities of IMC- 1 **, IMC- 2** and any **product** candidates we develop, if approved. Reliance on CMOs may expose us to more risk than if we were to manufacture our product candidates ourselves. We intend to have manufactured a sufficient clinical supply of IMC- 1 **and IMC- 2** drug substance to enable us to complete our clinical trials, and we have also engaged a CMO to provide clinical and commercial supply of the drug product. The facilities used to manufacture our product candidates must be inspected by the FDA and comparable foreign authorities. While we provide oversight of manufacturing activities, we do not and will not control the execution of manufacturing activities by, and are or will be essentially dependent on, our CMOs for ~~59~~ compliance with cGMP requirements for the manufacture of our product candidates. As a result, we are subject to the risk that our product candidates may have manufacturing defects that we have limited ability to prevent. If a CMO cannot successfully manufacture material that conforms to our specifications and the regulatory requirements, we will not be able to secure or maintain regulatory approval for the use of our product candidates in clinical trials, or for commercial distribution of our product candidates, if approved. In addition, we have limited control over the ability of our CMOs to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or comparable foreign regulatory authority finds deficiencies with or does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval or finds deficiencies in the future, we may need to find alternative manufacturing facilities, which would delay our development program and significantly impact our ability to develop, obtain regulatory approval for or commercialize our product candidates, if approved.

In addition, any failure to achieve and maintain compliance with these laws, regulations and standards could subject us to the risk that we may have to suspend the manufacture of our product candidates or that obtained approvals could be revoked. Furthermore, CMOs may breach existing agreements they have with us because of factors beyond our control. They may also terminate or refuse to renew their agreement at a time that is costly or otherwise inconvenient for us. If we were unable to find an adequate CMO or another acceptable solution in time, our clinical trials could be delayed, or our commercial activities could be harmed. We rely on and will continue to rely on CMOs to purchase from third- party suppliers the raw materials necessary to produce our product candidates. We do not and will not have control over the process or timing of the acquisition of these raw materials by our CMOs. Moreover, we currently do not have any agreements for the production of these raw materials. Supplies of raw material could be interrupted from time to time and we cannot be certain that alternative supplies could be obtained within a reasonable timeframe, at an acceptable cost, or at all. In addition, a disruption in the supply of raw materials could delay the commercial launch of our product candidates, if approved, or result in a shortage in supply, which would impair our ability to generate revenues from the sale of our product candidates. Growth in the costs and expenses of raw materials may also impair our ability to cost effectively manufacture our product candidates. There are a limited number of suppliers for the raw materials that we may use to manufacture our product candidates and we may need to assess alternative suppliers to prevent a possible disruption of the manufacture of our product candidates. Finding new CMOs or third- party suppliers involves additional cost and requires our management' s time and focus. In addition, there is typically a transition period when a new CMO commences work. Although we generally have not, and do not intend to, begin a clinical trial unless we believe we have on hand, or will be able to obtain, a sufficient supply of our product candidates to complete the clinical trial, any significant delay

in the supply of our product candidates or the raw materials needed to produce our product candidates, could considerably delay conducting our clinical trials and potential regulatory approval of our product candidates. As part of their manufacture of our product candidates, our CMOs and third- party suppliers are expected to comply with and respect the proprietary rights of others. If a CMO or third- party supplier fails to acquire the proper licenses or otherwise infringes the proprietary rights of others in the course of providing services to us, we may have to find alternative CMOs or third- party suppliers or defend against claims of infringement, either of which would significantly impact our ability to develop, obtain regulatory approval for or commercialize our product candidates, if approved. We intend to rely on third parties to conduct, supervise and monitor our clinical trials. If those third parties do not successfully carry out their contractual duties, or if they perform in an unsatisfactory manner, it may harm our business. We rely, and will continue to rely, on CROs, CRO- contracted vendors and clinical trial sites to ensure the proper and timely conduct of our clinical trials. Our reliance on CROs for clinical development activities limits our control over these activities, but we remain responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards. ~~60~~ We and our CROs will be required to comply with the **GLP** ~~Good Laboratory Practice~~ requirements for our preclinical studies and GCP requirements for our clinical trials, which are regulations and guidelines enforced by the FDA and are also required by comparable foreign regulatory authorities. Regulatory authorities enforce GCP requirements through periodic inspections of trial sponsors, principal investigators and clinical trial sites. If we or our CROs fail to comply with GCP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. There can be no assurance that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP requirements. In addition, our clinical trials must be conducted with product produced under cGMP requirements. Accordingly, if our CROs fail to comply with these requirements, we may be required 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 clinical trials. Our 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 do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for any other reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize any product candidate that we develop. As a result, our financial results and the commercial prospects for any product candidate that we develop would be harmed, our costs could increase, and our ability to generate revenue could be delayed. If our relationship with any 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' s 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 we 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. ● the number and type of our collaborations could adversely affect our attractiveness to future collaborators or acquirers; and ● the loss of, or a disruption in our relationship with, any one or more collaborators could harm our business. If any collaborations do not result in the successful development and commercialization of products or if one of our collaborators terminates its agreement with us, we may not receive any future research and development funding or milestone or royalty payments under such collaborations. If we do not receive the funding we expect under these agreements, our continued development of our product candidates could be delayed, and we may need additional resources to develop additional product candidates. All of the risks relating to product development, regulatory approval and commercialization described in this Annual Report on Form 10- K also apply to the activities of any collaborators and there can be no assurance

that our collaborations will produce positive results or successful products on a timely basis or at all. In addition, subject to its contractual obligations to us, if one of our collaborators is involved in a business combination or otherwise changes its business priorities, the collaborator might deemphasize or terminate the development or commercialization of our product candidates. If a collaborator terminates its agreement with us, we may find it more difficult to attract new collaborators and the perception of our business and our stock price could be adversely affected. ~~61~~ We may in the future collaborate with additional pharmaceutical and biotechnology companies for development and potential commercialization of therapeutic products. We face significant competition in seeking appropriate collaborators. Our ability to 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. If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to fund and undertake development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms or at all. If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our product candidates or bring them to market or continue to develop our programs, and our business may be materially and adversely affected. Risks Related to Healthcare Laws and Other Legal Compliance MattersEnacted and future healthcare legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our ~~development~~ **product** candidates, if approved, and may affect the prices we may set. In the United States and other jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes and proposed changes to the healthcare system that could affect our future results of operations. In particular, there have been and continue to be a number of initiatives at the U. S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare. For example, ~~in March 2010,~~ the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, or the ACA, ~~was passed, which~~ substantially changed the way healthcare is financed by both the government and private insurers and continues to significantly impact the U. S. pharmaceutical industry. Since its enactment, there have been executive, judicial and Congressional **50** challenges to certain aspects of the ACA. Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. It is unclear how future litigation or healthcare initiatives at the U. S. federal and state levels will impact our business, financial condition and results of operations. Complying with any new legislation or changes in healthcare regulation could be time consuming and expensive, resulting in a material adverse effect on our business. In addition, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been Congressional inquiries and proposed federal and state legislation designed to bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drugs. Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. We expect that additional U. S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U. S. federal government will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures. Individual states in the United States have also become increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third- party payors or other restrictions could harm our business, results of operations, financial condition and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and ~~62~~ other healthcare programs. This could reduce the ultimate demand for our product candidates or put pressure on our product pricing. In markets outside of the United States, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. We cannot predict the likelihood, nature, or extent of government regulation that may arise from future legislation or administrative action in the United States or any other jurisdiction. If we or any third parties we may engage are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or such third parties are not able to maintain regulatory compliance, our product candidates may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability. Our business operations and current and future relationships with investigators, healthcare professionals, consultants, third- party payors, patient organizations, and customers will be subject to applicable healthcare regulatory laws, which could expose us to penalties. Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third- party payors, patient organizations, and customers, may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute our product candidates, if approved. Such laws include: ● the U. S. federal Anti- Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving, or providing any remuneration (including any kickback, bribe, or certain rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, 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 U. S. federal and state healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the

statute or specific intent to violate it in order to have committed a violation. The U. S. federal Anti- Kickback Statute has been interpreted to **51** apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other hand; ● the U. S. federal false claims and civil monetary penalties laws, including the civil False Claims Act, or FCA, which, among other things, impose criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the U. S. federal government, claims for payment or approval that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U. S. federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the U. S. federal Anti- Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA. A claim includes " any request or demand " for money or property presented to the federal government. In addition, manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to " cause " the submission of false or fraudulent claims; ● the U. S. federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e. g., public or private) and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services. Similar to the U. S. federal Anti- Kickback Statute, a person or entity does ~~63~~ not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation; ● HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, which impose, among other things, specified requirements relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization by covered entities subject to the rule, such as health plans, healthcare clearinghouses and healthcare providers as well as their business associates that perform certain services involving the use or disclosure of individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates 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; ● the FDCA, which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices; ● the U. S. federal legislation commonly referred to as the Physician Payments Sunshine Act, enacted as part of the ACA, and its implementing regulations, which requires certain manufacturers of drugs, devices, biologics, and medical supplies that are reimbursable under Medicare, Medicaid, or the Children' s Health Insurance Program to report annually to the government information related to certain payments and other transfers of value to physicians and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members; and ● analogous U. S. state laws and regulations, including: state anti- kickback and false claims laws, which may apply to our business practices, including but not limited to, research, distribution, sales, and marketing arrangements and claims involving healthcare items or services reimbursed by any third- party payor, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry' s voluntary compliance guidelines and the relevant compliance **52** guidance promulgated by the U. S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information, which requires tracking gifts and other remuneration and items of value provided to healthcare professionals and entities; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available under such laws, it is possible that some of our business activities, including our consulting agreements and other relationships with physicians and other healthcare providers, some of whom receive stock or stock options as compensation for their services, could be subject to challenge under one or more of such laws. Ensuring that our current and future internal operations and business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, individual imprisonment, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements or oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non- ~~64~~ compliance with these laws, and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. If any of the physicians or other providers or entities with whom we expect to do business are found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs and imprisonment, which could affect our ability to operate our business. Further, defending against any such actions can be costly, time- consuming and may require significant personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. Any clinical trial programs we conduct or research collaborations we enter into in the European Economic Area may subject us to the General Data Protection Regulation. If we conduct clinical trial programs or enter into research collaborations in the European Economic Area, we may be subject to the

General Data Protection regulation, or GDPR. The GDPR applies extraterritorially and implements stringent operational requirements for processors and controllers of personal data, including, for example, high standards for obtaining consent from individuals to process their personal data, robust disclosures to individuals, a comprehensive individual data rights regime, data export restrictions governing transfers of data from the European Union, or EU, to other jurisdictions, short timelines for data breach notifications, limitations on retention of information, increased requirements pertaining to health data, other special categories of personal data and coded data and additional obligations if we contract third- party processors in connection with the processing of personal data. The GDPR provides that EU member states may establish their own laws and regulations limiting the processing of personal data, including genetic, biometric or health data, which could limit our ability to use and share personal data or could cause our costs to increase. If our or our partners' or service providers' privacy or data security measures fail to comply with the GDPR requirements, we may be subject to litigation, regulatory investigations, enforcement notices requiring us to change the way we use personal data and / or fines of up to € 20 million or up to 4 % of our total worldwide annual turnover of the preceding financial year, whichever is higher, as well as compensation claims by affected individuals, negative publicity, reputational harm and a potential loss of business and goodwill. **53** We are subject to environmental, health and safety laws and regulations, and we may become exposed to liability and substantial expenses in connection with environmental compliance or remediation activities. Our operations, including our development, testing and manufacturing activities, are subject to numerous environmental, health and safety laws and regulations. These laws and regulations govern, among other things, the controlled use, handling, release and disposal of and the maintenance of a registry for, hazardous materials and biological materials, such as chemical solvents, human cells, carcinogenic compounds, mutagenic compounds and compounds that have a toxic effect on reproduction, laboratory procedures and exposure to blood- borne pathogens. If we fail to comply with such laws and regulations, we could be subject to fines or other sanctions. As with other companies engaged in activities similar to ours, we face a risk of environmental liability inherent in our current and historical activities, including liability relating to releases of or exposure to hazardous or biological materials. Environmental, health and safety laws and regulations are becoming more stringent. We may be required to incur substantial expenses in connection with future environmental compliance or remediation activities, in which case, the production efforts of our third- party manufacturers or our development efforts may be interrupted or delayed. If we become profitable, our ability to use our net operating loss carryforwards and other tax attributes to offset future taxable income or taxes may be subject to limitations. As of December 31, ~~2022~~ **2023**, we had **U. S.** federal ~~and state~~ net operating loss ~~carry forwards~~ **carryforwards**, or NOLs, of approximately $ ~~22~~ **26**. ~~2~~ **5** million **and Georgia and Florida state NOLs of approximately $ 33. 7 million and $ 0. 9 million, respectively**. These net operating losses can be carried forward and applied against future ~~65~~ taxable income, if any. A full allowance for the value of the NOLs is provided for in our audited financial statements for the year of December 31, ~~2022~~ **2023** included in this Annual Report on Form 10- K. We cannot guarantee what the ultimate outcome or amount of the benefit we may receive from the NOLs, if any, will be. If we become profitable in the future, our ability to use net operating loss carryforwards and other tax attributes to offset future taxable income or reduce taxes may be subject to limitations. Risks Related to Our Intellectual PropertyOur patents may be challenged in courts or in patent offices which could result in the invalidation, narrowing or unenforceability of our patents and our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. There is no assurance that all the potentially relevant prior art relating to our patents and patent applications has been found, which can invalidate a patent or prevent a patent from issuing from a pending patent application. Even if patents do successfully issue and even if such patents further cover IMC- 1 **, IMC- 2** or any future product candidate, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed, invalidated, or held unenforceable. Any successful opposition to these patents or any other patents owned by or licensed to us could deprive us of rights necessary for the successful commercialization of any product candidates that we may develop. Further, if we encounter delays in regulatory approvals, the period during which we could market a product candidate under patent protection could be reduced. The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. For example, European patent law restricts the patentability of methods of treatment of the human body more than U. S. law does. However, in certain instances, the laws of the United States are more restrictive than those of foreign countries. For example, a recent series of U. S. Supreme Court cases has narrowed the types of subject matter considered eligible for patenting. Accordingly, certain diagnostic **54** methods are considered ineligible for patenting because they are directed to a " law of nature. " Further, publications of discoveries in scientific literature often lag the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in patent claims being narrowed, invalidated, held unenforceable, in whole or in part, or reduced in term. Such a result could limit our ability to stop others from using or commercializing similar or identical technology and products. Moreover, patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after it is filed. While various extensions may be available, the life of a patent is limited. Without patent protection for our current or

future product candidates, we may be open to competition from generic versions of such products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such **product** candidates might expire before or shortly after such **product** candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. ~~66~~ We may become subject to third parties' claims alleging infringement of their patents and proprietary rights, or we may need to become involved in lawsuits to protect or enforce our patents, which could be costly, time consuming, delay or prevent the development and commercialization of our product candidates or put our patents and other proprietary rights at risk. Our commercial success depends, in part, upon our ability to develop, manufacture, market and sell our product candidates without alleged or actual infringement, misappropriation or other violation of the patents and proprietary rights of third parties. Litigation relating to infringement or misappropriation of patent and other intellectual property rights in the pharmaceutical and biotechnology industries is common, including patent infringement lawsuits, interferences, oppositions and reexamination proceedings before the ~~U. S. Patent and Trademark Office, or~~ USPTO ~~,~~ and corresponding foreign patent offices. The various markets in which we plan to operate are subject to frequent and extensive litigation regarding patents and other intellectual property rights. In addition, many companies in intellectual property- dependent industries, including the biotechnology and pharmaceutical industries, have employed intellectual property litigation as a means to gain an advantage over their competitors. Numerous U. S., EU and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing product candidates. Some claimants may have substantially greater resources than we do and may be able to sustain the costs of complex intellectual property litigation to a greater degree and for longer periods of time than we could. In addition, patent holding companies that focus solely on extracting royalties and settlements by enforcing patent rights may target us. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the intellectual property rights of third parties. We may be subject to third- party claims including infringement, interference or derivation proceedings, post- grant review and inter partes review before the USPTO or similar adversarial proceedings or litigation in other jurisdictions. Even if we believe third party infringement claims are without merit, a court of competent jurisdiction could hold that these third- party patents are valid, enforceable and infringed, and the holders of any such patents may be able to block our ability to commercialize the applicable product candidate unless we obtained a license under the applicable patents, or until such patents expire or are finally determined to be **55** invalid or unenforceable. Proceedings challenging our patents or those that we license may also result in our patent claims being invalidated or narrowed in scope. Similarly, if our patents or patent applications are challenged during interference or derivation proceedings, a court may hold that a third- party is entitled to certain patent ownership rights instead of us. Further, if any third- party patents were held by a court of competent jurisdiction to cover aspects of our compositions, formulations, methods of manufacture, or methods of treatment, prevention or use, the holders of any such patents may be able to block our ability to develop and commercialize the applicable product candidate unless we obtained a license or until such patent expires or is finally determined to be invalid or unenforceable. In addition, defending such claims would cause us to incur substantial expenses and, if successful, could cause us to pay substantial damages, if we are found to be infringing a third party' s patent rights. If we are found to have infringed such rights willfully, the damages may be enhanced and may include attorneys' fees. Further, if a patent infringement suit is brought against us or our third- party service providers, our development, manufacturing or sales activities relating to the product or product candidate that is the subject of the suit may be delayed or terminated. As a result of patent infringement claims, or in order to avoid potential infringement claims, we may choose to seek, or be required to seek, a license from the third party, which may require us to pay license fees or royalties or both. These licenses may not be available on acceptable terms, or at all. Even if a license can be obtained on acceptable terms, the rights may be nonexclusive, which could give our competitors access to the same intellectual property rights. If we are unable to enter into a license on acceptable terms, we could be prevented from commercializing one or more of our product candidates, forced to modify such product candidates, or to cease some aspect of our business operations, which could harm our business significantly. Modifying our product candidates to design around third- party intellectual property rights may result in significant cost or delay to us and could prove to be technically infeasible. Any of these events, even if we were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business. In addition, if the breadth or strength of protection ~~67~~ provided the patents and patent applications we own or in- license is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates. If we were to initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that our patent is invalid or unenforceable. In patent litigation in the United States and in Europe, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, for example, lack of eligibility, lack of novelty, obviousness or non- enablement. Third parties might allege unenforceability of our patents because someone connected with prosecution of the patent withheld relevant information, or made a misleading statement, during prosecution. The outcome of proceedings involving assertions of invalidity and unenforceability during patent litigation is unpredictable. With respect to the validity of patents, for example, we cannot be certain that there is no invalidating prior art of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our product candidates. Furthermore, our patents and other intellectual property rights also will not protect our technology if competitors design around our protected technology without infringing on our patents or other intellectual property rights. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors view these announcements in

a negative light, the price of our common stock could be adversely affected. Finally, even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors view these announcements in a negative light, the price of our common stock could be adversely affected. Such litigation or proceedings could substantially increase our operating losses and reduce our resources available **56** for development activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have an adverse effect on our ability to compete in the marketplace. We may not identify relevant third- party patents or may incorrectly interpret the relevance, scope or expiration of a third- party patent, which might adversely affect our ability to develop, manufacture and market our product candidates. We cannot guarantee that any of our or our licensors' patent searches or analyses, including but not limited to the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third- party patent and pending application in the United States, Europe and elsewhere that is relevant to or necessary for the commercialization of our product candidates in any jurisdiction. For example, in the United States, certain filed applications that will not be filed outside the United States remain confidential until patents issue. Patent applications in the United States, EU and elsewhere are published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Therefore, patent applications covering our future product candidates, or their manufacture or use may currently be unpublished. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our product candidates or the use of our product candidates. The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent' s prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our ~~68~~ product candidates. We may incorrectly determine that our product candidates are not covered by a third- party patent or may incorrectly predict whether a third party' s pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States, the EU or elsewhere that we consider relevant may be incorrect, which may negatively impact our ability to develop and market our product candidates. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our product candidates. From time to time, we may identify patents or applications in the same general area as our products and product candidates. We may determine these third- party patents are irrelevant to our business based on various factors including our interpretation of the scope of the patent claims and our interpretation of when the patent expires. If the patents are asserted against us, however, a court may disagree with our determinations. Further, while we may determine that the scope of claims that will issue from a patent application does not present a risk, it is difficult to accurately predict the scope of claims that will issue from a patent application, our determination may be incorrect, and the issuing patent may be asserted against us. We cannot guarantee that we will be able to successfully settle or otherwise resolve such infringement claims. If we fail in any such dispute, in addition to being forced to pay monetary damages, we may be temporarily or permanently prohibited from commercializing our product candidates. We might, if possible, also be forced to redesign our product candidates so that we no longer infringe on the third- party intellectual property rights. Any of these events, even if we were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business. Changes in patent laws or patent jurisprudence could diminish the value of patents in general, thereby impairing our ability to protect our product candidates. As is the case with other biopharmaceutical and pharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical and pharmaceutical industries involve both technological complexity and legal complexity. Therefore, obtaining and enforcing biopharmaceutical and pharmaceutical patents is costly, time- consuming and inherently uncertain. **57** The U. S. has in recent years enacted and implemented wide ranging patent reform legislation. Additionally, the U. S. Supreme Court has ruled on several patent cases in recent years either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by Congress, the U. S. federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. Similarly, the complexity and uncertainty of European patent laws has also increased in recent years. In addition, the European patent system is relatively stringent in the type of amendments that are allowed during prosecution. Complying with these laws and regulations could limit our ability to obtain new patents in the future that may be important for our business. Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non- compliance with these requirements. Periodic maintenance and annuity fees on any issued patent are due to be paid to the USPTO and European and other patent agencies over the lifetime of a patent. In addition, the USPTO and European and other patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent failure to make payment of such fees or to comply with such provisions can in many cases be cured by payment of a late fee or by other ~~69~~ means in accordance with the applicable rules, there are situations in which such noncompliance will result in the abandonment or lapse of the patent or patent application, and the partial or complete loss of patent rights in the relevant jurisdiction. Non- compliance events that could result in abandonment or lapse of a patent or patent application include failure to

respond to official actions within prescribed time limits, non- payment of fees and failure to properly legalize and submit formal documents within prescribed time limits. If we or our licensors fail to maintain the patents and patent applications covering our product candidates or if we or our licensors otherwise allow our patents or patent applications to be abandoned or lapse, our competitors might be able to enter the market, which would hurt our competitive position and could impair our ability to successfully commercialize our product candidates in any indication for which they are approved. We enjoy only limited geographical protection with respect to certain patents and we may not be able to protect our intellectual property rights throughout the world. Filing, prosecuting and defending patents covering our product candidates in all countries throughout the world would be prohibitively expensive. Competitors may use our and our licensors' technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we and our licensors have patent protection, but enforcement is not as strong as that in the United States or the EU. These products may compete with our product candidates, and our and our licensors' patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. In addition, we may decide to abandon national and regional patent applications before grant. The grant proceeding of each national or regional patent is an independent proceeding which may lead to situations in which applications might in some jurisdictions be refused by the relevant patent offices, while granted by others. For example, unlike other countries, China has a heightened requirement for patentability, and specifically requires a detailed description of medical uses of a claimed drug. Furthermore, generic drug manufacturers or other competitors may challenge the scope, validity or enforceability of our or our licensors' patents, requiring us or our licensors to engage in complex, lengthy and costly litigation or other proceedings. Generic drug manufacturers may develop, seek approval for and launch generic versions of our products. It is also quite common that depending on the country, the scope of patent protection may vary for the same product candidate or technology. **58** The laws of some jurisdictions do not protect intellectual property rights to the same extent as the laws or rules and regulations in the United States and the EU, and many companies have encountered significant difficulties in protecting and defending such rights in such jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in other jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. Furthermore, while we intend to protect our intellectual property rights in our expected significant markets, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our product candidates. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate, which may have an adverse effect on our ability to successfully commercialize our product candidates in all of our expected significant foreign markets. If we or our licensors encounter difficulties in protecting, or are otherwise precluded from effectively protecting, the intellectual property rights important for our business in such jurisdictions, the value of these rights may be diminished, and we may face additional competition from others in those jurisdictions. ~~70~~ Some countries also have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, some countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our licensors is forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired. If we do not obtain patent term extension in the United States under the Hatch- Waxman Act and in foreign countries under similar legislation, thereby potentially extending the term of marketing exclusivity for our product candidates, our business may be materially harmed. Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U. S. non- provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired for a product, we may be open to competition from competitive medications, including generic medications. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such **product** candidates might expire before or shortly after such **product** candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. Depending upon the timing, duration and conditions of FDA marketing approval of our product candidates, we may be able to extend the term of a patent covering each product candidate under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch- Waxman Amendments and similar legislation in the EU. The Hatch- Waxman Amendments permit a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. The total patent term including the extension cannot exceed 14 years following regulatory approval. However, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for that product will be shortened and our competitors may **59** obtain approval to market competing products sooner. As a result, our revenue from applicable products could be reduced, possibly materially. Further, under certain circumstances, patent terms covering our products or product candidates may be extended for time spent during the pendency of the patent application in the USPTO (referred to as Patent Term Adjustment, or PTA). The laws and

regulations underlying how the USPTO calculates the PTA is subject to change and any such PTA granted by the USPTO could be challenged by a third- party. If we do not prevail under such a challenge, the PTA may be reduced or eliminated, resulting in a shorter patent term, which may negatively impact our ability to exclude competitors. Because PTA added to the term of patents covering pharmaceutical products has particular value, our business may be adversely affected if the PTA is successfully challenged by a third party and our ability to exclude competitors is reduced or eliminated. Intellectual property rights do not address all potential threats to our competitive advantage. The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business, or permit us to maintain our competitive advantage. The following examples are illustrative: ● others may be able to make products that are similar to IMC- 1 **, IMC- 2** or our future product candidates but that are not covered by the claims of the patents that we own or license from others; ~~71~~ ● others may independently develop similar or alternative technologies or otherwise circumvent any of our technologies without infringing our intellectual property rights; ● we or any of our collaborators might not have been the first to conceive and reduce to practice the inventions covered by the patents or patent applications that we own, license or will own or license; ● we or any of our collaborators might not have been the first to file patent applications covering certain of the patents or patent applications that we or they own or have obtained a license, or will own or will have obtained a license; ● it is possible that our pending patent applications will not lead to issued patents; ● issued patents that we own may not provide us with any competitive advantage, or may be held invalid or unenforceable, as a result of legal challenges by our competitors; ● our competitors might conduct research and development activities in countries where we do not have patent rights, or in countries where research and development safe harbor laws exist, and then use the information learned from such activities to develop competitive products for sale in our major commercial markets; ● ownership of our patents or patent applications may be challenged by third parties; and ● the patents of third parties or pending or future applications of third parties, if issued, may have an adverse effect on our business. Our reliance on third parties requires us to share our trade secrets, which increases the possibility that our trade secrets will be misappropriated or disclosed, and confidentiality agreements with employees and third parties may not adequately prevent disclosure of trade secrets and protect other proprietary information. We consider proprietary trade secrets or confidential know- how and unpatented know- how to be important to our business. We may rely on trade secrets or confidential know- how to protect our technology, **60** especially where patent protection is believed by us to be of limited value. Because we expect to rely on third parties to manufacture IMC- 1 **, IMC- 2** and any future product candidates, and we expect to collaborate with third parties on the development of IMC- 1 **, IMC- 2** and any future product candidates, we must, at times, share trade secrets with them. We also conduct joint research and development programs that may require us to share trade secrets under the terms of our research and development partnerships or similar agreements. However, trade secrets or confidential know- how can be difficult to maintain as confidential. To protect this type of information against disclosure or appropriation by competitors, our policy is to require our employees, consultants, contractors and advisors to enter into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements or other similar agreements with us prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. However, current or former employees, consultants, contractors and advisers may unintentionally or willfully disclose our confidential information to competitors, and confidentiality agreements may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. The need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know- how and trade secrets, a competitor' s discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may have an adverse effect on our business and results of operations. Enforcing a claim that a third party obtained illegally and is using trade secrets or confidential know- how is expensive, ~~72~~ time consuming and unpredictable. The enforceability of confidentiality agreements may vary from jurisdiction to jurisdiction. In addition, these agreements typically restrict the ability of our advisors, employees, third- party contractors and consultants to publish data potentially relating to our trade secrets, although our agreements may contain certain limited publication rights. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of our agreements with third parties, independent development or publication of information by any of our third- party collaborators. A competitor' s discovery of our trade secrets would impair our competitive position and have an adverse impact on our business. If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected. Our unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential collaborators or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our unregistered trademarks or trade names. Over the long term, if we are unable to successfully register our trademarks and trade names and establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively, and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely impact our financial condition or results of operations. We may need to license certain intellectual property from third parties, and such licenses may not be available or may not be available on commercially reasonable terms. A third party may hold intellectual property, including patent rights that are important or necessary to the development or commercialization of IMC- 1 **, IMC- 2** or our future product candidates. It may be necessary for us to use the patented or proprietary technology of third

parties to commercialize IMC- 1 ~~or~~**, IMC- 2** ~~our~~ **or our future 61** product candidates, in which case we would be required to obtain a license from these third parties. Such a license may not be available on commercially reasonable terms, or at all, which could materially harm our business. At this time, we are unaware of any intellectual property that interferes with ours or is complementary and needed to commercialize IMC- 1 **or IMC- 2** . We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of their former employers or other third parties. We employ individuals who were previously employed at other biotechnology or pharmaceutical companies. Although we seek to protect our ownership of intellectual property rights by ensuring that our agreements with our employees, collaborators and other third parties with whom we do business include provisions requiring such parties to assign rights in inventions to us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of our employees' former employers or other third parties. We may also be subject to claims that former employers or other third parties have an ownership interest in our patents. Litigation may be necessary to defend against these claims. There is no guarantee of success in defending these claims, and if we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership or right to use. Even if we are successful, litigation could result in substantial cost and be a distraction to our management and other employees. ~~73~~ Our proprietary information may be lost, or we may suffer security breaches. In the ordinary course of our business, we collect and store sensitive data, including intellectual property, clinical trial data, proprietary business information, personal data and personally identifiable information of our clinical trial subjects and employees, in our data centers and on our networks. The secure processing, maintenance and transmission of this information is critical to our operations. Despite our security measures, our information technology and infrastructure may be vulnerable to attacks by hackers or breached due to employee error, malfeasance or other disruptions. Although, to our knowledge, we have not experienced any such material security breach to date, any such breach could compromise our networks and the information stored there could be accessed, publicly disclosed, lost or stolen. Any such access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, significant regulatory penalties, disruption of our operations, damage to our reputation and cause a loss of confidence in us and our ability to conduct clinical trials, which could adversely affect our reputation and delay our clinical development of our product candidates. Risks Related to Our Employees, Managing Our Growth and Our OperationsOur future success depends on our ability to retain our key personnel and to attract, retain and motivate qualified personnel. We are highly dependent on the development, regulatory, commercialization and business development expertise of the executive team, as well as the other principal members of our management, scientific and clinical teams. Although we have employment agreements, offer letters or consulting agreements with our executive officers, these agreements do not prevent them from terminating their services at any time. If we lose one or more of our executive officers or key employees, our ability to implement our business strategy successfully could be seriously harmed. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop product candidates, gain regulatory approval, and commercialize new products. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these additional key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and **62** clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be engaged by entities other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain highly qualified personnel, our ability to develop and commercialize product candidates will be limited. We expect to expand our development, regulatory, and sales and marketing capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations. We expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of development, regulatory affairs and sales and marketing. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities or acquire new facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations. ~~74~~ We may engage in acquisitions that could disrupt our business, cause dilution to our stockholders or reduce our financial resources. In the future, we may enter into transactions to acquire other businesses, products or technologies. If we do identify suitable candidates, we may not be able to make such acquisitions on favorable terms, or at all. Any acquisitions we make may not strengthen our competitive position, and these transactions may be viewed negatively by customers or investors. We may decide to incur debt in connection with an acquisition or issue our common stock or other equity securities to the stockholders of the acquired company, which would reduce the percentage ownership of our existing stockholders. We could incur losses resulting from undiscovered liabilities of the acquired business that are not covered by the indemnification we may obtain from the seller. In addition, we may not be able to successfully integrate the acquired personnel, technologies and operations into our existing business in an effective, timely and nondisruptive manner. Acquisitions may also divert management attention from day- to- day responsibilities, increase our expenses and reduce our cash available for operations and other uses. We cannot predict the number, timing or size of future acquisitions or the effect that any such transactions might have on our operating results. Our business and operations would suffer in the event of system failures. Our computer systems, as well as those of our CROs and other contractors and consultants, are vulnerable to damage from computer

viruses, unauthorized access, natural disasters (including hurricanes), terrorism, war and telecommunication and electrical failures. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs. For example, the loss of preclinical or clinical trial data from completed, ongoing or planned trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of or damage to our data or applications, or inappropriate disclosure of personal, confidential or proprietary information, we could incur liability and the further development of IMC- 1 **, IMC- 2** or any ~~other~~ **future** product candidate could be delayed. **63** Risks Related to Our Common StockIf we are unable to maintain listing of our common stock on the Nasdaq Capital Market or another national stock exchange, it may be more difficult for our stockholders to sell their shares of common stock. Nasdaq requires issuers to comply with certain standards to remain listed on its exchange. ~~We have~~ **On November 2, 2023, we** received a delisting notice from Nasdaq as a result of the closing bid price of our common stock being below $ 1. 00 per share for 30 consecutive business days. Our common stock may be involuntarily delisted from Nasdaq if we fail to regain compliance with the minimum closing bid price requirement of $ 1. 00 per share. **The notice has no immediate effect on the continued listing status of the Company' s common stock on the Nasdaq Capital Market, and, therefore, the Company' s listing remains fully effective. However, if the Company fails to regain compliance with Nasdaq' s listing rules, it could be subject to suspension and delisting proceedings.** If we are unable to maintain our listing on Nasdaq, it may become more difficult for our stockholders to sell our common stock in the public market **. In addition** , ~~and~~ **in the event the Company' s securities are delisted, broker- dealers have certain regulatory burdens imposed upon** ~~the~~ **them** ~~price~~ **, which may discourage broker- dealers from effecting transactions in the Company' s securities, further limiting the liquidity** of **such securities. A determination that** our common stock ~~may be adversely affected due~~ **is a " penny stock " will require brokers trading in our common stock** to ~~the likelihood of decreasing liquidity~~ **adhere to more stringent rules and possibly** ~~resulting~~ **result in a reduced level of trading activity in the secondary trading market for our common stock. Such delisting** from **The Nasdaq Capital Market and continued** ~~delisting. In addition, it may inhibit~~ or ~~preclude~~ **further declines in the Company' s share price could also greatly impair** our ability to raise additional ~~funding~~ **necessary capital through equity or debt financing, and could significantly increase the ownership dilution to stockholders caused by our issuing equity in financing or other transactions. Further, if we are delisted, we would also incur additional costs under state blue sky laws in connection with any sales of our securities** . The market price of our common stock is highly volatile, which could result in substantial losses for holders of our common stock. The market price of our common stock is highly volatile and is subject to wide fluctuations in response to a variety of factors, including the following: ● any delay in submitting an NDA and any adverse development or perceived adverse development with respect to the FDA' s review of that NDA; ● failure to successfully develop and commercialize IMC- 1 **, IMC- 2** or any future **product** ~~candidate~~ **candidates** ; ~~75~~ ● inability to obtain additional funding; ● regulatory or legal developments in the United States and other countries applicable to IMC- 1 **, IMC- 2** or any other **product** ~~candidate~~ **candidates** ; ● adverse regulatory decisions; ● changes in the structure of healthcare payment systems; ● inability to obtain adequate product supply for IMC- 1 **, IMC- 2** or any other **product** candidate, or the inability to do so at acceptable prices; ● introduction of new products, services or technologies by our competitors; ● failure to meet or exceed financial projections we provide to the public; **64** ● failure to meet or exceed the estimates and projections of the investment community; ● changes in the market valuations of companies similar to ours; ● market conditions in the pharmaceutical and biotechnology sectors, and the issuance of new or changed securities analysts' reports or recommendations; ● announcements of significant acquisitions, strategic collaborations, joint ventures or capital commitments by us or our competitors; ● significant lawsuits, including patent or shareholder litigation, and disputes or other developments relating to our proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies; ● additions or departures of key scientific or management personnel; ● sales of our common stock by us or our shareholders in the future; ● trading volume of our common stock; ● general economic, industry and market conditions; and ● the other factors described in this " Risk Factors " section. In addition, the stock markets have experienced extreme price and volume fluctuations that have affected and continue to affect the market prices of equity securities of many companies. These fluctuations have often been unrelated or disproportionate to the operating performance of those companies. Broad market and industry factors, as well as general economic, political, regulatory and market conditions, may negatively affect the market price of our common stock, regardless of our actual operating performance. We could be subject to securities class action litigation. In the past, securities class action litigation has often been brought against companies following a decline in the market price of their securities. This risk is especially relevant for us because biotechnology companies have experienced significant share price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management' s attention and resources, which could harm our business. ~~76~~ If securities or industry analysts do not publish research or reports about our business, or if they issue an adverse or misleading opinion regarding our common stock, our stock price and trading volume could decline. The trading market for our common stock depends, in part, on the research and reports that securities or industry analysts may publish about us or our business. We do not have any control over these analysts. If our financial performance fails to meet analyst estimates or one or more of the analysts who cover us downgrade our common stock or change their opinion of our common stock, our share price would likely decline. If one or more of these analysts cease coverage of us or fail to regularly publish reports on us, we could lose visibility in the financial markets, which could cause our share price or trading volume to decline. We do not intend to pay dividends on our common stock so any returns will be limited to the value of our stock. We have never declared or paid any cash dividends on our common stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not **65** anticipate declaring or paying any cash dividends for the foreseeable future. As a result, capital appreciation, if any, of our common stock would be our stockholder' s sole source of gain on an investment in our common stock for the foreseeable future ~~. Our principal stockholders and management own a significant percentage of our stock and will~~

~~be able to exert significant control over matters subject to stockholder approval. Our executive officers, directors, holders of 5 % or more of our capital stock and their respective affiliates beneficially own approximately 16 % of our outstanding voting stock. Therefore, these stockholders may be able to significantly influence us through this ownership position. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents or approval of any merger, sale of assets or other major corporate transaction. The interests of this group of stockholders may not always coincide the interests of our public market investors and they may act in a manner that advances their best interests and not necessarily those of other stockholders, including seeking a premium value for their common stock, and might affect the prevailing market price for our common stock~~ . We are subject to significant increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives and corporate governance practices. As a public company, and particularly after we no longer qualify as an emerging growth company, we incur significant legal, accounting and other expenses. The Sarbanes- Oxley Act of 2002 (" SOX "), the Dodd- Frank Wall Street Reform and Consumer Protection Act, the listing requirements of Nasdaq, and other applicable securities rules and regulations impose various requirements on U. S. reporting public companies, including the establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations increase our legal and financial compliance costs and make some activities more time- consuming and costly. For example, these rules and regulations may make it more expensive for us to obtain director and officer liability insurance, which in turn could make it more difficult for us to attract and retain qualified senior management personnel or members for our board of directors. In addition, these rules and regulations are often subject to varying interpretations, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. Pursuant to Section 404 of SOX, we are required to furnish a report by our senior management on our internal control over financial reporting. While we remain an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. ~~77~~ To comply with Section 404, we are required to engage in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and maintain a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by Section 404. If we identify one or more material weaknesses, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements. **66** If we fail to establish and maintain proper and effective internal control over financial reporting, our operating results and our ability to operate our business could be harmed. Ensuring that we have adequate internal financial and accounting controls and procedures in place so that we can produce accurate financial statements on a timely basis is a costly and time- consuming effort that needs to be reevaluated frequently. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with generally accepted accounting principles. In connection with our initial public offering, we began the process of documenting, reviewing and improving our internal controls and procedures for compliance with Section 404 of SOX, which requires annual management assessment of the effectiveness of our internal control over financial reporting. Implementing any appropriate changes to our internal controls may distract our officers and employees, entail substantial costs to modify our existing processes and take significant time to complete. These changes may not, however, be effective in maintaining the adequacy of our internal controls and any failure to maintain that adequacy or consequent inability to produce accurate financial statements on a timely basis, could increase our operating costs and harm our business. In addition, investors' perceptions that our internal controls are inadequate or that we are unable to produce accurate financial statements on a timely basis may harm our common share price and make it more difficult for us to effectively market and sell our service to new and existing customers. We are an " emerging growth company, " and a " smaller reporting company " and the reduced reporting requirements applicable to emerging growth companies and smaller reporting companies may make our common stock less attractive to investors. We are an " emerging growth company, " as defined in the Jumpstart Our Business Startups Act, or JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including exemption from compliance with the auditor attestation requirements of Section 404, reduced disclosure obligations regarding executive compensation and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the closing of our IPO, (b) in which we have total annual gross revenue of at least $ 1. 07 billion or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock held by non- affiliates exceeds $ 700 million as of the end of our prior second fiscal quarter, and (2) the date on which we have issued more than $ 1. 0 billion in non- convertible debt during the prior three- year period. Even after we no longer qualify as an emerging growth company, we may still qualify as a " smaller reporting company, " which would allow us to take advantage of many of the same exemptions from disclosure requirements, including not being required to comply with the auditor attestation requirements of Section 404 and reduced disclosure obligations regarding executive compensation. ~~78~~ In addition, under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards until such time as those standards apply to private

companies. We intend to take advantage of the extended transition period for adopting new or revised accounting standards under the JOBS Act as an emerging growth company. As a result of this election, our financial statements may not be comparable to companies that comply with public company effective dates. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our share price may be more volatile. **67** Provisions in our certificate of incorporation and bylaws and under Delaware law could make an acquisition of our company, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management. Provisions in our certificate of incorporation and our bylaws may discourage, delay or prevent a merger, acquisition or other change in control of our company that stockholders may consider favorable, including transactions in which our stockholders might otherwise receive a premium for their shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions include those establishing: ● Advance notice bylaw provisions for proposals from stockholders for presentation at annual meetings; and ● Forum selection bylaw provisions. Because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the General Corporation Law of the State of Delaware, which prohibits a person who owns in excess of 15 % of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15 % of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner. Our certificate of incorporation and our bylaws will contain exclusive forum provisions for certain claims, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees. Our certificate of incorporation and our bylaws, to the fullest extent permitted by law, provide that the Court of Chancery of the State of Delaware will be the exclusive forum for any derivative action or proceeding brought on our behalf; any action asserting a breach of fiduciary duty; any action asserting a claim against us arising pursuant to the General Corporation Law of the State of Delaware, our certificate of incorporation, or our bylaws; or any action asserting a claim against us that is governed by the internal affairs doctrine. Moreover, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all claims brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder and our bylaws provide that the federal district courts of the United States of America will, to the fullest extent permitted by law, be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, or a Federal Forum Provision. Our decision to adopt a Federal Forum Provision followed a decision by the Supreme Court of the State of Delaware holding that such provisions are facially valid under Delaware law. While there can be no assurance that federal or state courts will follow the holding of the Delaware Supreme Court or determine that the Federal Forum Provision should be enforced in a particular case, application of the Federal Forum Provision means that suits brought by our stockholders to ~~79~~ **enforce any duty or liability created by the Securities Act must be brought in federal court and cannot be brought in state court. Section 27 of the Exchange Act creates exclusive federal jurisdiction over all claims brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder and neither the exclusive forum provision nor the Federal Forum Provision applies to suits brought to enforce any duty or liability created by the Exchange Act. Accordingly, actions by our stockholders to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder must be brought in federal court. Our stockholders will not be deemed to have waived our compliance with the federal securities laws and the regulations promulgated thereunder. 68**