

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-K

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2020

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Commission file number: 001-39811

VIRIOS THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State of Other Jurisdiction of incorporation or Organization)

85-4314201
(I.R.S. Employer Identification No.)

44 Milton Avenue, Alpharetta, GA
(Address of principal executive offices)

30009
(Zip code)

Registrant's telephone number, including area code: (866) 620-8655

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Trading Symbol(s)	Name Of Each Exchange On Which Registered
Common Stock, \$0.001 Par Value per Share	VIRI	Nasdaq Capital Market

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

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act.

Yes No

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

Indicate by check mark whether the Registrant has submitted electronically; every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.0405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes No

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

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

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

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

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

As of June 30, 2020, the last business day of the Registrant's most recently completed second fiscal quarter, there was no established public trading market for the Registrant's equity securities.

The number of outstanding shares of the Registrant's Common Stock as of March 15, 2021 was 8,330,390.

Documents Incorporated by Reference

Part III incorporates certain information by reference from the definitive proxy statement to be filed by the registrant in connection with the 2021 Annual Meeting of Stockholders (the "Proxy Statement") with the Securities and Exchange Commission pursuant to Regulation 14A not later than 120 days after the end of the year ended December 31, 2020, provided that if such Proxy Statement is not filed within such period, such information will be included in an amendment to this Form 10-K to be filed within such 120-day period.

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CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K, including "Management's Discussion and Analysis of Financial Condition and Results of Operations" in Item 7, contains forward-looking statements. All statements other than statements of historical facts contained in this Annual Report on Form 10-K, including statements regarding our future results of operations and financial position, business strategy, prospective products, product approvals, research and development costs, timing and likelihood of success, plans and objectives of management for future operations and future results of anticipated products, are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "expect," "plan," "anticipate," "could," "intend," "target," "project," "contemplate," "believe," "estimate," "predict," "potential" or "continue" or the negative of these terms or other similar expressions. The forward-looking statements in this Annual Report on Form 10-K are only predictions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements speak only as of the date of this Annual Report on Form 10-K and are subject to a number of risks, uncertainties and assumptions described under the sections in this Annual Report on Form 10-K titled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere in this Annual Report on Form 10-K. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond our control, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Moreover, we operate in an evolving environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

SUMMARY OF RISK FACTORS

The following is a summary of the principal risks described below in Part I, Item 1A "Risk Factors" in this Annual Report on Form 10-K. We believe that the risks described in the "Risk Factors" section are material to investors, but other factors not presently known to us or that we currently believe are immaterial may also adversely affect us. The following summary should not be considered an exhaustive summary of the material risks facing us, and it should be read in conjunction with the "Risk Factors" section and the other information contained in this Annual Report on Form 10-K.

Risks Related to Our Financial Position and Need for Additional Capital

- 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 IMC-1 and if this drug does not receive regulatory approval or is not successfully commercialized, our business may be harmed.

- We may face future business disruption and related risks resulting from the outbreak of the novel coronavirus 2019 (COVID-19).
- 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 IMC-1 or any other 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, if approved, may be smaller than we anticipate.
- We may never obtain approval for or commercialize IMC-1 or any other development 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.
- IMC-1 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, 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 intend to rely on CMOs for the production of commercial supply of IMC-1, 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 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.
- Recent U.S. tax legislation may materially adversely affect our financial condition, results of operations and cash flows.

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.
- Our business and operations would suffer in the event of system failures.

Risks Related to Our Common Stock

- The market price of our common stock may be volatile and fluctuate substantially.
- We do not anticipate paying any cash dividends on our common stock in 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.
- We have identified a material weakness in our internal control over financial reporting.
- Provisions in our certificate of incorporation and bylaws and under Delaware law could make an acquisition of our company more difficult and may prevent attempts by our stockholders to replace or remove our current management.
- 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.

PART I

Item 1. Business

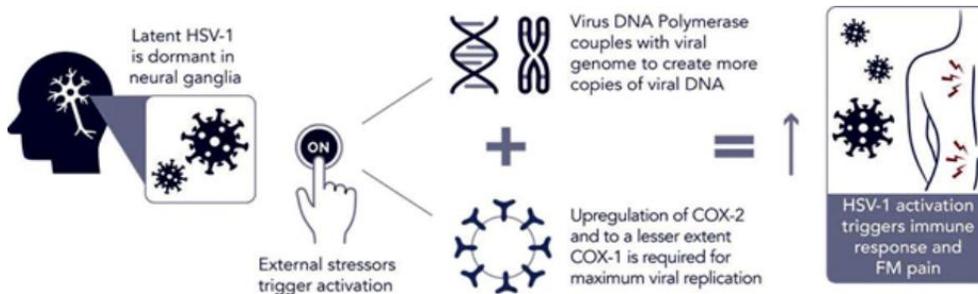
Our Company

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"). Overactive immune response related to activation of tissue resident Herpes Simplex Virus-1 ("HSV-1") has been postulated to be a potential root cause of chronic illnesses such as FM, irritable bowel disease ("IBS"), chronic fatigue syndrome and other functional somatic syndromes, all of which are characterized by a waxing and waning manifestation of disease. While not completely understood, there is general agreement in the medical community that activation of HSV-1 is triggered by some form of environmental and/or health stressor. Our lead candidate, IMC-1, is a novel, proprietary, fixed dose combination of famciclovir and celecoxib. IMC-1 represents a novel combination, dual mechanism antiviral therapy designed to synergistically suppress HSV-1 activation and replication, with the end goal of reducing viral mediated disease burden.

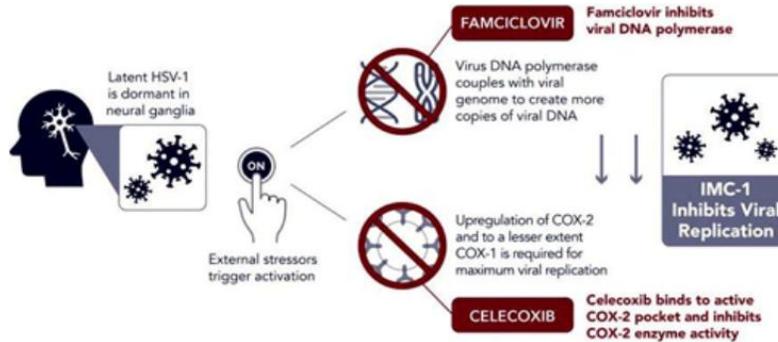
IMC-1 combines two specific mechanisms of action purposely designed to inhibit HSV-1 activation and replication, thereby keeping HSV-1 in a latent (dormant) state or "down-regulating" HSV-1 from a lytic (active) state back to latency. The famciclovir component of IMC-1 inhibits viral DNA replication. The celecoxib component of IMC-1 inhibits cyclooxygenase-2 ("COX-2") and to a lesser degree COX-1 enzymes, used by HSV-1 to amplify or accelerate its own replication. We are unaware of any other antivirals in development for the treatment of FM. This novel approach was a germane consideration in FDA designating IMC-1 for fast-track review status for the treatment of FM. IMC-1 has also been granted a synergy patent based on the fact that neither of the individual components has proven effective in the management of fibromyalgia, yet the dual mechanism combination therapy generated a result in preliminary studies that appears to be greater than the sum of its parts.

Dormant HSV-1 is Reactivated by External Triggers and Amplifies

Its Own Replication via Cyclooxygenase (COX 1 and COX 2) Enzymes

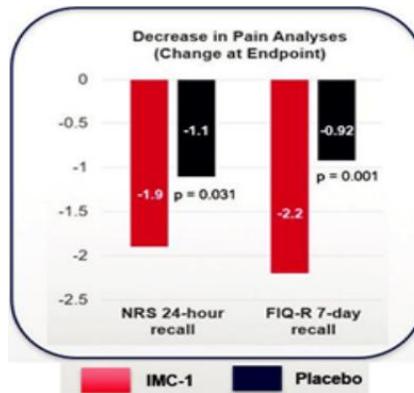


**IMC-1's Novel, Synergistic Antiviral Mechanism Suppresses Viral Replication,
Demonstrates FM Treatment Effect**



The potential of IMC-1 in FM is underpinned by statistically significant improvement versus placebo in the primary endpoint of pain reduction as demonstrated in a 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 treatment.

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.



IMC-1 also exhibited consistent improvement across several secondary FM treatment outcomes, including 50% responder analysis, 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 did not meet statistical significance. 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 in the IMC-1 group were a non-ST segment elevation myocardial infarction and a facial cellulitis and one 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 trial, we held an end of Phase 2 meeting with the FDA, and 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 are now seeking to take IMC-1 from Phase 2a proof-of-concept to a larger scale Phase 2b clinical trial of IMC-1 for the treatment of FM. The Phase 2b and chronic toxicology studies are planned components of the registration package supporting Phase 3 requirements.

For the Phase 3 program, we intend to run either one or two qualifying pivotal trials demonstrating the safety and efficacy of IMC-1 treating patients with fibromyalgia. The first 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. All patients from the first Phase 3 study will be offered the opportunity to enroll into an open label safety follow-on extension study with all on IMC-1. If this study meets its primary efficacy endpoint, we plan to negotiate with FDA to either accept the large Phase 2b to qualify as an adequate and well-controlled trial as part of the Phase 3 program or conduct a second pivotal study.

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.

There are approximately 3.6 million patients in the U.S. that have been diagnosed with FM, with approximately 2 million 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 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 products approved 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 \geq 7 and SSS score \geq 5 OR WPI = 4-6 and SSS score \geq 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 fibromyalgia is valid irrespective of other diagnoses and does not exclude the presence of other clinically important illnesses.

Fibromyalgia: A Serious Condition with Unmet Medical Need

FM is associated with increased mortality due to suicide or accident. Researchers evaluating over 8,186 patients with FM across three different sites in the US 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 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 (PDUFA V), 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. March 26, 2014 the FDA held a public meeting with patients suffering from FM. The meeting was chaired by 5 panelists from 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 effective, many FM patients described that they could not adhere to treatment regimens because they were unable to tolerate treatment side effects. 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 2007

- a. 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 2009

- a. 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.

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. In a survey developed by the National Fibromyalgia Association (“NFA”) that was completed by 2,596 FM patients via the Internet in 2007, respondents reported using over twenty different medications (polypharmacy), including the use of opioids, to manage their FM. The survey questionnaire was developed by the NFA and the questionnaire underwent several rounds of testing to improve its face validity, content validity, clarity and readability before it was posted on the Internet. The questionnaire consisted of 121 items and was available online at the website of the National Fibromyalgia Association.

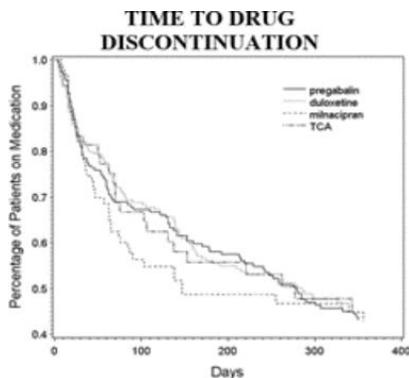
The table below shows the percentage use of different therapies for FM based on data from a 2012 study lead by Dr. Rebecca Robinson, a fibromyalgia researcher, and her colleagues. The study evaluated the burden of illness and treatment patterns for patients with fibromyalgia from July 2008 through May 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 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.

Patient Prescription Usage (2008-2010)

Type of Treatment	% Treated Patients
Antidepressants	
Cymbalta (duloxetine)	26.8%
SSRIs	13.1%
Savella (milnacipran)	8.9%
Other antidepressants	7.8%
Amitriptyline	5.4%
Analgesics	
Opioids (incl. tramadol)	39.5%
NSAIDs	26.6%
Anticonvulsants	
Lyrica (pregabalin)	24.5%
Gabapentin	11.2%
Sedatives	
Benzodiazepines	15.2%
Nonbenzodiazepine sedative/hypnotics	12.9%
Muscle Relaxants	
Cyclobenzaprine	12.9%
Others	
Stimulants	5.2%
Other medications	<5% each

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 an 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

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: HSV-1 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 CNS-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 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, it results in an abnormal stress or herpes virus mediated-immune response. Herpes viruses are unique in that they remain in a dormant state (latency) in neuronal nuclei 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 of HSV-1 is postulated to perpetuate FM symptoms in these patients.

Our novel therapeutic is directed at interrupting the ongoing immune response by suppressing HSV-1, 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 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 herpes viruses, including HSV-1, 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 HSV-1 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 HSV-1 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.

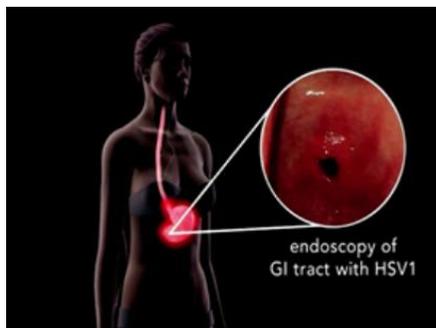
The anti-herpes virus MOA of the nucleoside analogs (which include famciclovir) is well characterized and this drug class has been used to treat viruses over decades. In its active state famciclovir is initially phosphorylated to a monophosphate form, after which it is converted to penciclovir triphosphate 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 Development

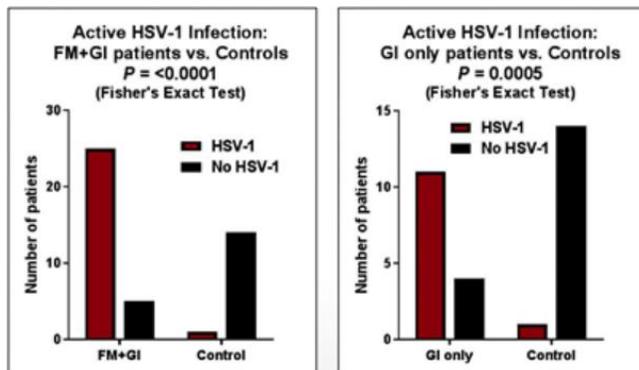
The initial clinical evidence supporting the development of an antiviral plus COX-2/NSAID combination to address FM was first derived through clinical observation in patients with IBS. IBS patients treated with famciclovir, who were serendipitously also placed on celecoxib to treat their arthritis, showed 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) HSV-1 infection, resulting in a continuous nociceptive stimulation and immune response. The cyclical process of virus reactivation and lytic infection of HSV-1 perpetuates FM symptoms. To interrupt and reverse viral reactivation and immune response, and resultant continuous nociceptive stimulation requires the suppression of HSV-1, reverting it into a dormant (latency) status. We believe the coaction (synergy) of therapeutic agents with different antiviral properties is required to suppress HSV-1 and reverse the symptoms of FM. Famciclovir, a nucleoside analog DNA inhibitor, inhibits the replication of viral DNA. HSV-1 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 HSV-1 to latency.

IMC-1 interrupts the chronic dysfunctional immune response to HSV-1 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 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, alter treatment outcomes in FM, and potentially a number of other chronic pain conditions in the Somatic Symptom Disorders where HSV-1 may play a role.

Biomarker — Gastrointestinal Tissue Study to see if HSV-1 is present in IBS/FM



The 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 HSV-1 infection, where active FM is resultant upon reactivation of HSV-1 virus infection. We have postulated that HSV-1 infected nerve tissue located in the gastric mucosa provides a site for biopsy and represents an excellent site to confirm active HSV-1 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 ICP8, a protein only found in active 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. The study is not required to be submitted to the IND.

PRID-201 Phase 2a Study of IMC-1 In Patients With Fibromyalgia (NCT01850420)

PRID-201 Phase 2a Study Design

The PRID-201 study represents the first placebo-controlled study evaluating the safety and 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 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") measure during clinic visits, as well as with the 7-day recall average pain score recorded on the Revised Fibromyalgia Impact Questionnaire ("FIQ-R"). 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-201 Clinical Study Report submitted to the Investigational New Drug ("IND") 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, 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 10 = worst imaginable pain) that was recorded during clinic visits. The FIQ-R is a disease specific instrument designed to assess the impact of fibromyalgia 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 Analysis

Pain Analysis	Placebo LS Change @ Endpoint (SE)	IMC-1 LS Change @ Endpoint (SE)	Contrast (SE)	P- Value
NRS 24-hour recall, MMRM LOCF/BOCF Imputation @ 16 weeks	-1.1 (0.28)	-1.9 (0.28)	-0.8 (0.37)	0.031
FIQ-R 7-days recall, MMRM LOCF/BOCF Imputation @ 16 weeks	-0.92 (0.30)	-2.2 (0.30)	-1.25 (0.38)	0.001

If the estimated change from baseline for a patient’s pain scores met or exceeded 50%, they were considered a 50% pain responder. In the pain responder analysis, 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.

PRID-201 Phase 2a Secondary Endpoint 50% Reduction of Pain Analyses with Curve Fit

50% Pain Responder Analysis	Measure	Placebo Responders (%)	Placebo Non-Responders (%)	IMC-1 Responders (%)	IMC-1 Non-Responders	P-Value
Week 16 Visit, 50% Reduction	NRS	11 (15.1)	62 (84.9)	20 (30.3)	46 (69.7)	0.009
Week 16 Visit, 50% Reduction	FIQ-R Pain	12 (16.9)	59 (83.1)	25 (37.9)	41 (62.1)	0.001

As 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

30% Pain Responder Analysis	Measure	Placebo Responders (%)	Placebo Non-Responders (%)	IMC-1 Responders (%)	IMC-1 Non-Responders	P-Value
Week 16 Visit, 30% Reduction	NRS	23 (31.5)	50 (68.5)	28 (42.4)	38 (57.6)	0.052
Week 16 Visit, 30% Reduction	FIQ-R Pain	20 (28.2)	51 (71.8)	29 (43.9)	37 (56.1)	0.012

Past 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 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 Result

PGIC Analysis	Placebo Responders (%)	Placebo Non-Responders (%)	IMC-1 Responders (%)	IMC-1 Non-Responders	P- Value
Week 6 Visit	14 (19.2)	59 (80.8)	26 (37.7)	43 (62.3)	0.040
Week 12 Visit	13 (17.8)	60 (82.2)	26 (37.7)	43 (62.3)	0.005
Week 16 Visit	14 (19.2)	59 (80.8)	23 (33.3)	46 (66.6)	0.040

FIQ-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).

PRID-201 Phase 2a Secondary Endpoint Fibromyalgia Impact Questionnaire-Revised & PROMIS Fatigue Results

Outcomes Measure	Method	Placebo Baseline	IMC-1 Baseline	Placebo LS Change (SE)	IMC-1 LS Change (SE)	Contrast (SE)	P- Value
FIQ-R	Week 16 MMRM LOCF/BOCF	56.81 (73)	54.28 (69)	-7.87 (2.33)	-17.54 (2.40)	-9.67 (3.05)	0.002
PROMIS Fatigue	Week 16 MMRM LOCF/BOCF	65.83 (73)	65.55 (69)	-2.68 (0.93)	-6.65 (0.96)	-3.96 (1.22)	0.001

The FIQ-R demonstrated statistical significance in all 3 domains (see below).

Analysis of FIQ-R Domain Scores with LOCF/BOCF Imputation

Week 16 FIQ-R Analysis LOCF/BOCF Imputation*	LS Mean (SE) Change from Baseline		Contrast (SE)	P- Value**
	Placebo N = 71	IMC-1 N = 66		
Functional Domain	-5.44 (2.32)	-14.29 (2.40)	-8.85 (3.03)	0.004
Overall Impact Domain	-1.89 (0.61)	-4.29 (0.63)	-2.40 (0.79)	0.003
Symptoms 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 Medication

Tramadol use was prospectively identified as the only rescue therapy by IMC. The proportion of patients taking tramadol for fibromyalgia rescue was defined as all tramadol usage from the concomitant medication logs. The proportion of patients who took rescue therapy for fibromyalgia was summarized by treatment group. The use of tramadol was significantly higher in the placebo group compared to the IMC-1 group.

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.

Secondary Endpoints	P Value
Pain Responder Analysis – 50% Pain Reduction	
• 24 Hour Recall NRS	p=0.009
• 7 Day Recall NRS	p=0.001
Pain Responder Analysis – 30% Pain Reduction	
24 Hour Recall NRS @ week 16	p=0.052
7 Day Recall NRS @ week 16	p=0.012
PROMIS (NIH) Fatigue Assessment	p=0.001
PGIC - Patient’s Global Impression of Change	P=0.040
FIQ-R - Revised Fibromyalgia Impact Questionnaire Total Score	p=0.002
FIQ-R – Functional Domain	p=0.004
FIQ-R – Overall Impact Domain	p=0.003
FIQ-R – Symptoms Domain	p=0.004
Use of Rescue Medication	p=0.037

PRID-201 Phase 2a Safety

Tolerability 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 3 serious adverse events (“SAEs”) were reported. The 2 in the IMC-1 group were a Non-ST Segment Elevation Myocardial Infarction and a Facial Cellulitis and 1 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; however, the patient's underlying coronary artery disease and strong family history of premature cardiac disease suggest that other causal factors were also involved.

PRID-201 Phase 2a Adverse Event Report

Adverse Events Reported for ≥5% of the Patients in Either Treatment Group

Adverse Event	Placebo N=73	IMC-1 N=69
Any Event	57 (78.1)%	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)%

Adverse Events Reported for ≥5% of the Patients in Either Treatment Group

Adverse Event	Placebo N=73	IMC-1 N=69
Constipation	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 IMC-1 (5.8%; n=4). Increased treatment adherence in actual clinical practice is important in any chronic therapy.

Category	Placebo	IMC-1	Totals
Randomized	74	69	143
ITT Population*	73	69	142
Safety Population	73	69	142
Per-Protocol Population	72	67	139
Prematurely discontinued from study	29 (39.2%)	12 (17.4%)	41 (28.7%)
Completed all protocol assessments, regardless of discontinuation of study drug	62 (83.8%)	62 (89.9%)	124 (86.7%)
Completed 16 weeks on study medication	45 (60.8%)	57 (82.6%)	102 (71.3%)
Discontinuation reasons:			
Adverse event (p=0.012)	12 (16.2%)	4 (5.8%)	16 (11.2%)
Therapeutic failure	12 (16.2%)	5 (7.2%)	17 (11.9%)
Non-compliance	1 (1.4%)	0	1 (0.7%)
Withdrawal of consent	3 (4.1%)	2 (2.9%)	5 (3.5%)
Lost to follow-up	1 (1.4%)	1 (1.4%)	2 (1.4%)

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; chronic fatigue was one of the three key factors of an ideal FM product that was discussed at the FM PFDD meeting. The preliminary clinical 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 Questionnaire

An 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 times
- TMJ: 5 times
- Insomnia: 1.7 times
- Neck and back pain: 2.3 times
- Anxiety: 2.8 times
- Depression: 1.6 times

This 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.

Regulatory and Development Timeline

We 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 is eligible for submission to the FDA for approval under Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act, or 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 to rely upon FDA's previous findings of safety and effectiveness, and extensively reference several sections of the US Prescribing Information for Famvir (famciclovir), from Novartis, and Celebrex (celecoxib), from Pfizer, the reference drugs for our program. The 505(b)(2) NDA filing will rely on portions of the development programs conducted by the sponsors of the reference drugs, as described in the FDA-approved US Prescribing Information.

At the conclusion of our phase 2a clinical trial in 2017 we held an end-of-phase 2 meeting with the FDA and conducted a subsequent conference call with the FDA in November 2017. As a result of those meetings the FDA has provided us with a defined path forward to Phase 3, including agreement to initiate a Phase 2b and/or Phase 3 trial after we provide animal toxicology study data, conduct a human PK study with celecoxib

and famciclovir combined in 1 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.

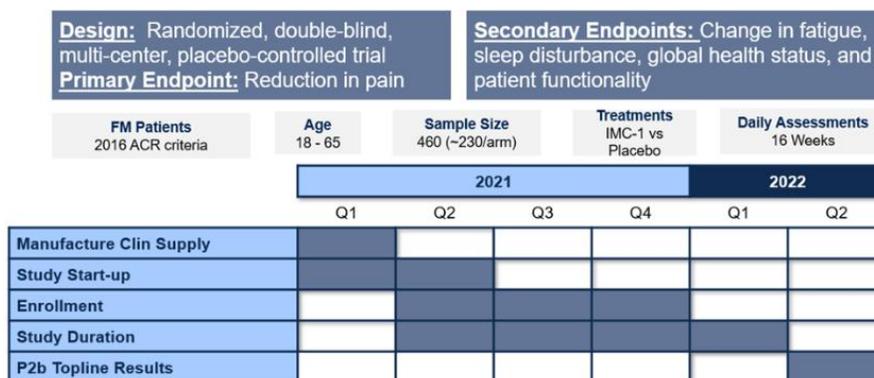
We have also successfully completed the required 90-day sub-chronic toxicology studies with the oral combination of IMC-1 that we believe support the optimal dosing to be used in the Phase 2b and Phase 3 trials. This GLP 13-week general toxicology study with toxico-kinetics and a recovery period has 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 INC-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 are planning for the required chronic toxicology studies will be run in parallel to the Phase 2b trial. These studies consist of a six-month rat and a nine-month dog study. The development of the 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.

The FDA has agreed to our 505(b)(2) filing plan.

The Phase 2b FM trial is expected to start in the first quarter of 2021 with topline results by the second quarter of 2022. The multifactorial Phase 3 trial is planned to start immediately following the Phase 2b trial results. The Phase 2b trial design is exhibited below.

Phase 2b Study Design and Timeline



Market and Competition

The three pharmaceutical agents currently approved for the treatment of fibromyalgia, 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 \$3.6 billion in the US 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 to avoid opioid narcotic medications for treating fibromyalgia. Evidence shows these drugs are not of helpful to most people with fibromyalgia, 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 U.S. 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.

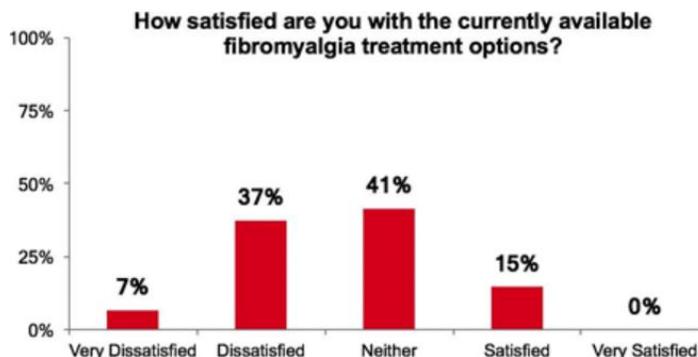
Our recently completed 2020 assessment provided an updated disease review, forecast and valuation for FM and IBS for the US and Ex-US markets. Both assessments show that significant unmet medical needs exist in the fibromyalgia treatment armamentarium, as well as the IBS treatment armamentarium, highlighting the commercial potential for a new medicine that proves to be safe and effective as determined by the FDA.

Primary Research Background

In 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 US. 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), 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 Pipeline

Both 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 US 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.

Other Market Opportunities

Each 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 HSV-1 could play an important role in the pathogenesis of FM which we believe was confirmed in our Phase 2a trial, with wide scale clinical utility to be further examined and tested in our planned Phase 2b trial. If successfully proven, we believe that IMC-1 can be disruptive to the market and can change the way FM is treated. The 2020 assessment showed IMC-1’s novel MOA and positive Phase 2a results differentiate it mechanistically from current and pipeline FM products. Importantly, the 2014 assessment with 6 health insurance payors has confirmed potential first-line usage and favorable pricing and access potential.

Intellectual Property

We 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, 2020, our portfolio of owned patents totaled 20 issued patents consisting of 12 issued U.S. patents and 8 issued foreign patents. This includes three Composition of Matter patents, including a Synergistic Patent, and two Method of Use patents in the US, all of which relate to IMC-1. Exclusivity with all patents is through 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 celecoxib

Issued Foreign IMC-1 Patents

- European Patent (EP 2 811 833 & 2 965 759)
- Japan (JP 5855770 & 6422848)
- Australia (AU 2013217110)
- China (CN 104144606)
- Korea (KR 10-1485748)
- Canada (2,863,812)

US Patents Covering Other Anti-Viral Combinations

- US 9,682,051 (acyclovir/meloxicam)
- US 8,623,882 (acyclovir/diclofenac)
- US 9,259,405 (famciclovir/diclofenac)
- US 9,642,824 (valacyclovir/diclofenac)
- US 9,980,932 (valacyclovir/meloxicam)
- US 10,543,184 (acyclovir/celecoxib)
- US 10,632,087 (famciclovir/meloxicam)

Foreign Patents Covering Other Anti-Viral Combinations

- Europe Patent (EP 2 965 759)

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, or 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.

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 US 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 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 Agreements

In 2012, we entered into a Know-How License Agreement, or the License Agreement, with the University of Alabama. In consideration for the License Agreement, the University of Alabama received membership interests 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 UA 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 Marketing

If IMC-1 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.

Manufacturing

We 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.

Government Regulation

The 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 Products

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act (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. 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, or 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, or 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, or 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, or 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.
- Compliance with any post-approval requirements, including the potential requirement to implement a Risk Evaluation and Mitigation Strategy, or REMS, and the potential requirement to conduct post-approval studies.

Preclinical Studies

Preclinical 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.

Clinical Trials

Clinical 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 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.

Marketing Approval

Assuming 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, or 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 FDA because the FDA has approximately two months to make a "filing" decision.

In addition, under the Pediatric Research Equity Act of 2003, or PREA, 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 risk evaluation and mitigation strategy, or 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, 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 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 Programs

The 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.

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, or FDASIA, 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 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 Pathway

The 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.

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 Exclusivity

Under 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.

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.

Post-Approval Requirements

Drugs 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.
- 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 Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of our product candidate, IMC-1, or any other for which we may seek regulatory approval. Sales in the U.S. will 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 or any other 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 Requirements

We 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 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 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 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 Competition

Section 505(b)(2) NDAs

As 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 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 Process

The 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, or 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 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 Listing

In 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 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 Exclusivity

In 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 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 States

To 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 28 Member States of the EU plus Norway, Iceland and Liechtenstein) and many other foreign jurisdictions, we must obtain separate regulatory approvals. More concretely, in the EEA, medicinal products can only be commercialized after obtaining a Marketing Authorization, or 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, or 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 States of the EEA assess the risk-benefit balance of the product based on scientific criteria concerning its quality, safety and efficacy.

Data and Marketing Exclusivity

In 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.

Orphan Drug Designation

In 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 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 PIP.

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 Resources

As of December 31, 2020, we had three 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.

Facilities

Our offices are in Alpharetta, Georgia. We believe that our facilities are adequate to meet our current needs.

Item 1A. Risk Factors

An 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 before making an investment in our common stock. 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, and you could lose all or part of your investment.

Risks Related to Our Financial Position and Need for Additional Capital

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 clinical stage biopharmaceutical company with a limited operating history and have incurred losses since our formation. We incurred net losses of \$10,346,395 and \$2,473,627 for each of the years ended December 31, 2020 and 2019. As of December 31, 2020, we had an accumulated deficit of \$27,965,105. 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 and any other candidates through clinical development, complete clinical trials, seek regulatory approval and commercialize the drug or any other candidates, if approved. The costs of advancing 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 candidates to marketing approval in even a single 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:

- commence our Phase 2b trial, or conduct clinical trials for any other indications or other candidates;
- establish sales, marketing, distribution, and compliance infrastructures to commercialize our drug, if approved, and for any other candidates for which we may obtain marketing approval;
- maintain, expand and protect our intellectual property portfolio;
- 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 candidates or technologies.

Furthermore, our ability to successfully develop, commercialize and license any candidates and generate product revenue is subject to substantial additional risks and uncertainties, as described 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.

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 IMC-1, if we receive regulatory approval. We will require additional capital for the further development and potential commercialization of IMC-1 and may also need to raise additional funds sooner to pursue a more accelerated development of IMC-1. 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 \$29,795,366 as of December 31, 2020, will enable us to fund our operations through the end of 2022. We have based this estimate on assumptions that may prove to be wrong, and we could deploy our available capital resources sooner 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 any other future candidates;
- clinical development plans we establish for IMC-1 and any other future candidates;
- obligation to make royalty and non-royalty sublicense receipt payments to third-party licensors, if any, under our licensing agreements;
- number and characteristics of 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, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. 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 candidate development or future commercialization efforts.

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 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, you should not rely upon the results of any particular quarterly or annual period as indications of future operating performance.

Risks Related to Development, Clinical Testing, Manufacturing and Regulatory Approval

We are heavily dependent on the success of IMC-1, our most advanced candidate, which is still under clinical development, and if this drug does not receive regulatory approval or is not successfully commercialized, our business may be harmed.

We do not have any products that have gained regulatory approval. Currently, our lead clinical stage candidate is IMC-1. 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 in a timely manner. We cannot commercialize IMC-1 in the United States without first obtaining regulatory approval from the FDA; similarly, we cannot commercialize IMC-1 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 for a target indication, we must demonstrate with substantial evidence gathered in preclinical studies and clinical trials, generally including two adequate and well-controlled clinical trials, and, with respect to approval in the United States, to the satisfaction of the FDA, that IMC-1 is safe and effective

for use for that target indication and that the manufacturing facilities, processes and controls are adequate. Even if IMC-1 were to successfully obtain approval from the FDA and comparable foreign regulatory authorities, any approval might contain significant limitations related to use restrictions for specified 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 contains significant limitations, we may not be able to obtain sufficient funding or generate sufficient revenue to continue the development of any other 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, 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 recent outbreak of the novel coronavirus 2019 (COVID-19) or from another pandemic, epidemic or outbreak of an infectious disease, any of which could have a material adverse effect on our business.

The development of our drug candidates could be disrupted and materially adversely affected in the future by a pandemic, epidemic or outbreak of an infectious disease like the recent outbreak of COVID-19. For example, as a result of measures imposed by the governments in regions affected by COVID-19 businesses and schools have been suspended due to quarantines or “stay at home” orders intended to contain this outbreak. The spread of COVID-19 from China to other countries has resulted in the Director General of the World Health Organization declaring the outbreak of COVID-19 as a Public Health Emergency of International Concern (PHEIC), based on the advice of the Emergency Committee under the International Health Regulations (2005), and on March 12, 2020, the President of the United States imposed international travel restrictions between the US and Europe to supplement the existing international travel restrictions between the US and certain Asian countries and on March 13, 2020, declared a national emergency in response to the likely spread of COVID-19 to the U.S. COVID-19 continues to spread globally and, as of July 2020, has spread to over 150 countries, including the United States. While the COVID-19 outbreak is still in its early stages, international stock markets continue to reflect the uncertainty associated with the slow-down in the Chinese, US and European economies and the reduced levels of international travel experienced since the beginning of January 2020. The significant declines in the Dow Industrial Average and other domestic and international stock indices at the end of February and during March and April 2020 were largely attributed to the adverse effects the pandemic has had on the world’s economies. We are still assessing our business plans and the impact COVID-19 may have on our ability to advance the development of our drug candidates, including delays in starting or completing clinical trials, or to raise financing to support the development of our drug candidates, but no assurances can be given that this analysis will enable us to avoid part or all of any impact from the spread of COVID-19 or its consequences, including downturns in business sentiment generally or in our sector in particular.

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 extent to which the coronavirus impacts our business will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of the coronavirus and the actions to contain the coronavirus or treat its impact, 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 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;
- 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 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 or any other 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 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 or any other candidates. We are not permitted to market any of our product candidates in the United States until we receive regulatory approval of a NDA from the FDA.

- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a candidate is safe and effective for its proposed indication;
- serious and unexpected drug-related side effects experienced by participants in our clinical trials or by individuals using drugs similar to our candidates, or other products containing the active ingredient in our candidates;
- 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;
- we may be unable to demonstrate that a 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 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 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 candidate in the United States or abroad, we must demonstrate with substantial evidence from well-controlled clinical trials, and to the satisfaction of the FDA or foreign regulatory agencies, that such 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 candidates are promising, such data may not be sufficient to support approval by the FDA and other regulatory authorities. The planned IMC-1 FM phase 2b trial will be an expanded trial that includes both primary and secondary endpoints consistent with previously approved medicines. If IMC-1 achieves

statistically significant effects on the pain reduction endpoints, and IMC-1 continues to be well tolerated, we plan to seek approval of IMC-1 based on the results of a single phase 3 clinical study, as opposed to the traditional approach of conducting two or more phase 3 studies. A single-study approach is permissible in certain circumstances, but such circumstances are exceptional and FDA may not agree with that proposed approach, and thus we may be required to conduct two phase 3 trials.

The FDA or any foreign regulatory bodies can delay, limit or deny approval of our 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;
- 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;
- 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 or another candidates, which would significantly harm our business, results of operations and prospects.

In addition, the FDA or the applicable 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;
- 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;
- our ability to maintain patient consents;
- the risk that patients enrolled in clinical trials will drop out of the trials before completion; and
- delays or difficulties in enrollment and completion of studies due to the COVID 19 pandemic.

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 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 or any other 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 2 study discontinued due to adverse events at a rate lower than patients treated with placebo. The most common adverse events IMC-1 patients experienced were gastrointestinal events and headache, in both cases at rates lower than placebo. There were three serious adverse events observed in the Phase 2 study, two on patients treated with IMC-1, and one for a placebo treated patient.

If unacceptable side effects arise in the development of our 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 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.

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;
- 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, if approved, may be smaller than we anticipate.

We expect to initially seek approval for IMC-1 for fibromyalgia in the US. 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 candidate and we may be unable to obtain, or may be delayed in obtaining, marketing approval for any of our development 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 candidates or may conclude after review of our data that our application is insufficient to obtain marketing approval of our development candidates. If the FDA does not accept or approve our NDAs for our development 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 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.

Even if we obtain FDA approval for IMC-1 or any other candidates in the United States, we may never obtain approval for or commercialize IMC-1 or any other development 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 by regulatory authorities in other countries, and regulatory approval in one country does not guarantee regulatory approval in any other country.

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

Even if we obtain regulatory approval for IMC-1 or any development candidate, we will still face extensive and ongoing regulatory requirements and obligations and any development candidates, if approved, may face future development and regulatory difficulties.

Any 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.

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;
- 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. 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, that 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 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 or one or more of our other candidates. 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 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 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 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 or any other 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 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.

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 Commercialization

We 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 IMC-1 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 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 our other products.

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, are marketed in numerous FDA-approved single-ingredient generic products that copy the 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 using these ingredients. Such generic competitors could apply those processes to develop equivalent generic versions of IMC-1. 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 IMC-1 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-1 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 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 FDA at any time after approval of the IMC-1 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 filing, FDA would be barred from approving the generic version for 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, 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. 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 or other proposed indications for IMC-1, in an attempt to lower the costs to their patients.

The successful commercialization of IMC-1 and any other 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 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, 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 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.

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 or any 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 or any 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 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 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;
- the availability of third-party coverage and adequate reimbursement;
- the prevalence and severity of any side effects; and
- 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, if approved.

We do not have any infrastructure for the sales, marketing or distribution of IMC-1, 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 product candidate we develop, if approved, 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, if approved, in the United States and Europe. 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 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;
- 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, if approved, for certain markets overseas; however, we cannot assure you 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, we may be forced to delay the potential commercialization of the drug or reduce the scope of our sales or marketing activities. If we need to increase our expenditures to fund commercialization activities for IMC-1 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 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:

- 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;
- 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.

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 Parties

Our 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 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 intend to rely on CMOs for the production of commercial supply of IMC-1, 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 and any 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 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 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, including our Phase 2b trials of IMC-1. 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.

We and our CROs will be required to comply with the 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. We cannot assure you 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.

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 Matters

Enacted and future healthcare legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our development 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, as amended by the Health Care and Education Reconciliation Act, or collectively the ACA, was enacted, which substantially changed the way healthcare is financed by both governmental and private insurers. Among the provisions of the ACA, those of greatest importance to the pharmaceutical and biotechnology industries include the following:

- an annual, non-deductible fee payable by any entity that manufactures or imports certain branded prescription drugs and biologic agents (other than those designated as orphan drugs), which is apportioned among these entities according to their market share in certain government healthcare programs;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;
- new requirements to report certain financial arrangements with physicians and teaching hospitals, including reporting "transfers of value" made or distributed to prescribers and other healthcare providers and reporting investment interests held by physicians and their immediate family members;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs and biologics that are inhaled, infused, instilled, implanted, or injected;
- extension of a manufacturer's Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs thereby potentially increasing a manufacturer's Medicaid rebate liability;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;
- establishment of a Center for Medicare Innovation at the Centers for Medicare & Medicaid Services, or CMS, to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending;
- expansion of the entities eligible for discounts under the Public Health Service program; and
- a licensure framework for follow on biologic products.

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. The current presidential administration and Congress will likely continue to seek to modify, repeal, or otherwise invalidate all, or certain provisions of, the ACA. This includes enactment of the Tax Cuts and Jobs Act, which, among other things, removes penalties for not complying with the ACA's individual mandate to carry health insurance. It is uncertain the extent to which any such changes may impact our business or financial condition.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. For example, the Budget Control Act of 2011, resulted in aggregate reductions of Medicare payments to providers of 2% per fiscal year. These reductions went into effect in April 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2027 unless additional action is taken by Congress. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Additionally, the orphan drug tax credit was reduced as part of a broader tax reform. These new laws or any other similar laws introduced in the future may result in additional reductions in Medicare and other health care funding, which could negatively affect our customers and accordingly, our financial operations.

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.

Executive action by the President may also adversely affect the prices we may set for our drug products, if approved. In July 2020, and on September 13, 2020, President Trump announced new executive orders that would purport to limit drug prices paid by governmental insurance programs, including a "most favored nation" order to limit the prices paid by Medicare to those prices charged for the drug in other countries, such as in the European Union, which have strict price control regimes. The details and potential impact of the executive orders are not yet clear, and the orders may be challenged in court, but the outcome of any such litigation cannot be predicted.

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 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 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 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 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-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 Euros or up to 4% of the 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.

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.

Recent U.S. tax legislation may materially adversely affect our financial condition, results of operations and cash flows.

Recently-enacted U.S. tax legislation has significantly changed the U.S. federal income taxation of U.S. corporations, including by reducing the U.S. corporate income tax rate, limiting interest deductions, and revising the rules governing NOLs. Many of these changes are effective immediately, without any transition periods or grandfathering for existing transactions. The legislation is unclear in many respects and could be subject to potential amendments and technical corrections, as well as interpretations and implementing regulations by the Treasury and Internal Revenue Service, or the IRS, any of which could lessen or increase certain adverse impacts of the legislation. In addition, it is unclear how these U.S. federal income tax changes will affect state and local taxation, which often uses federal taxable income as a starting point for computing state and local tax liabilities.

The reduction of the corporate tax rate under the legislation may cause a reduction in the economic benefit of deferred tax assets available to us. Furthermore, under the legislation, although the treatment of tax losses generated before December 31, 2018 has generally not changed, tax losses generated in calendar year 2019 and beyond will only be able to offset 80% of taxable income. This change may require us to pay federal income taxes in future years despite generating a loss for federal income tax purposes in prior years.

While some of the changes made by the tax legislation may adversely affect us in one or more reporting periods and prospectively, other changes may be beneficial on a going-forward basis. We intend to work with

our tax advisors and auditors to determine the full impact that the recent tax legislation as a whole will have on us. We urge our investors to consult with their legal and tax advisors with respect to such legislation.

Risks Related to Our Intellectual Property

Our 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 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 Supreme Court Cases has narrowed the types of subject matter considered eligible for patenting. Accordingly, certain diagnostic 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 candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

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 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

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 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, applications filed before November 29, 2000 and certain applications filed after that date 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 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. In addition, the America Invents Act (AIA) which was passed in September 2011, resulted in significant changes to the U.S. patent system.

An important change introduced by the AIA is that, as of March 16, 2013, the United States transitioned to a "first-to-file" system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention. A third party that files a patent application in the USPTO after that date but before us could therefore be awarded a patent covering an invention of ours even if we made the invention before it was made by the third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application, but circumstances could prevent us from promptly filing patent applications on our inventions.

Among some of the other changes introduced by the AIA are changes that limit where a patentee may file a patent infringement suit and provide opportunities for third parties to challenge any issued patent with the USPTO. This applies to all of our U.S. patents, even those issued before March 16, 2013. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U.S. federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action.

Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. It is not clear what, if any, impact the AIA will have on the operation of our business. However, the AIA and its implementation could increase the uncertainties and costs surrounding the prosecution of our or our licensors' patent applications and the enforcement or defense of our or our licensors' issued patents.

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 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 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.

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.

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 candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to 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

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 or our future product candidates but that are not covered by the claims of the patents that we own or license from others;
- 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,

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 and any future product candidates, and we expect to collaborate with third parties on the development of IMC-1 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 advisors 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, 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 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 our 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.

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.

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 Operations

Our 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. Upon the completion of the Corporate Conversion, our current President, Richard Burch, will resign his position as President and will be appointed to our board of directors.

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 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.

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 or any other product candidate could be delayed.

Risks Related to Our Common Stock

An active trading market for our common stock may not develop.

If an active trading market for our common stock does not develop, you may not be able to sell your shares quickly or at the market price. Our ability to raise capital to continue to fund operations by selling shares of our common stock and our ability to acquire other companies or technologies by using shares of our common stock as consideration may also be impaired.

The market price of our common stock may be volatile and fluctuate substantially, which could result in substantial losses for holders of our common stock.

The market price of our common stock is likely to be highly volatile and may be subject to wide fluctuations in response to a variety of factors, including the following:

- any delay in the commencement, enrollment and ultimate completion of our Phase 2b trial of IMC-1;
- 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 or any future candidate;
- inability to obtain additional funding;
- regulatory or legal developments in the United States and other countries applicable to IMC-1 or any other candidate;
- adverse regulatory decisions;
- changes in the structure of healthcare payment systems;
- inability to obtain adequate product supply for IMC-1 or any other 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;
- 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.

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 will depend, 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.

Because we do not anticipate paying any cash dividends on our common stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain.

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 anticipate declaring or paying any cash dividends for the foreseeable future. As a result, capital appreciation, if any, of our common stock would be your sole source of gain on an investment in our common stock for the foreseeable future. See "Dividend Policy" for additional information.

We have broad discretion in the use of the net proceeds from our IPO and may not use them effectively.

We have broad discretion in the application of the net proceeds from our IPO. You may not agree with our decisions, and our use of the proceeds may not yield any return on your investment. Because of the number and variability of factors that will determine our use of the net proceeds from our IPO, their ultimate use may vary substantially from their currently intended use. Our failure to apply the net proceeds of our IPO effectively could compromise our ability to pursue our growth strategy and we might not be able to yield a significant return, if any, on our investment of these net proceeds.

A significant portion of our total outstanding shares is restricted from immediate resale but may be sold into the market in the near future, which could cause the market price of our common stock to decline significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market after our IPO, or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. Of our issued and outstanding common stock, all of the shares sold in our IPO will be freely transferable without restrictions or further registration under the Securities Act of 1933, as amended (the "Securities Act") except for any shares acquired by our affiliates, as defined in Rule 144 under the Securities Act. The remaining shares outstanding after our IPO are restricted as a result of securities laws, lock-up agreements or other contractual restrictions that restrict transfers for 180 days, or in the case of our directors and officers for twelve months, after the date of our IPO. See "Shares Eligible for Future Sale — Lock-Up Agreements."

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 18.4% 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. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders. The interests of this group of stockholders may not always coincide with your interests or the interests of other stockholders 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 will incur 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 will incur significant legal, accounting and other expenses that we did not incur previously. The Sarbanes-Oxley Act of 2002, or 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 will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect that 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, or Section 404, we will be 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. To prepare for eventual compliance with Section 404, once we no longer qualify as an emerging growth company or are not entitled to other available exemptions, we will be engaged 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, potentially 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 implement 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.

We have identified a material weakness in our internal control over financial reporting. If we are unable to remediate this material weakness, or if we experience additional material weaknesses in the future, we may not be able to accurately or timely report our financial condition or results of operation.

We have identified a material weakness in our internal control over financial reporting related to the segregation of duties, financial statement reporting, stock-based compensation and general technology controls. Inability to fully segregate responsibilities can result in error and create opportunity for fraud. Similarly, the use of information technology can affect the manner in which transactions are initiated, authorized, recorded, processed, and reported. Failure to properly secure the access rights to significant applications can result in errors and/or irregularities in the course of performing day-to-day activities and enable unauthorized personnel to retrieve and modify financial statement data. Our structure and size does not enable us to fully segregate financial statement accounting and operational functions, including financial statements and critical supporting schedules. Further, we currently do not have automated technology controls that ensure proper segregation of duties exists, including but not limited to, general ledger access, vendor management, and the ability to authorize and release wire transactions and other payments. We can give no assurance that material weaknesses in our internal control over financial reporting will not be identified in the future. Any such failure could also adversely affect the results of the periodic management evaluations and, to the extent we are no longer an emerging growth company, the annual auditor attestation reports regarding the effectiveness of our internal control over financial reporting that will be required under Section 404 of the Sarbanes-Oxley Act of 2002. Internal control deficiencies could also cause investors to lose confidence in our reported financial information.

We are an “emerging growth company,” and the reduced reporting requirements applicable to emerging growth 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.

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.

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 that will become effective upon the Corporate Conversion 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, will 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 DGCL, 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 will 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 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.

Any person or entity purchasing or otherwise acquiring or holding any interest in any of our securities shall be deemed to have notice of and consented to our exclusive forum provisions, including the Federal Forum Provision. These provisions may limit our stockholders' ability to bring a claim in a judicial forum they find favorable for disputes with us or our directors, officers, or other employees, which may discourage lawsuits against us and our directors, officers, and other employees. Alternatively, if a court were to find the choice of forum provision contained in our certificate of incorporation and/or bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, operating results and financial condition.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

We do not own or lease any real property. We run a virtual model and have a mailing address in Alpharetta, Georgia.

Item 3. Legal Proceedings

From time to time we may be involved in claims that arise during the ordinary course of business. Although the results of litigation and claims cannot be predicted with certainty, we do not currently have any pending litigation to which we are a party or to which our property is subject that we believe to be material. Regardless of the outcome, litigation can be costly and time consuming, and it can divert management's attention from important business matters and initiatives, negatively impacting our overall operations.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Market Information

Our common stock has been listed on The Nasdaq Capital Market ("Nasdaq") under the symbol "VIRI" since our initial public offering on December 16, 2020.

Holders of Record

As of February 25, 2021, there were approximately 207 holders of record of shares of our common stock. This number does not reflect the beneficial holders of our common stock who hold shares in street name through brokerage accounts or other nominees.

Dividend Policy

We have never declared or paid any cash dividends on our common stock. We currently intend to retain all available funds and any future earnings to support our operations and finance the growth and development of our business. We do not intend to pay cash dividends on our common stock for the foreseeable future.

Recent Sales of Unregistered Securities

On July 17, 2020, we issued membership interest representing 0.5% of our outstanding membership interest to Dr. Pridgen.

On August 19, 2020, we issued membership interest representing 4.5% of our outstanding membership interest to Dr. Pridgen.

In July 2020, previously issued convertible promissory notes with an aggregate principal amount of \$1.47 million and an aggregate amount of accrued interest of \$0.17 million converted into 4.09% of our outstanding membership interests and Warrants to purchase \$366,250 of our membership interests that accompanied those convertible promissory notes were not exercised and thus forfeited.

On November 30, 2020, previously issued convertible promissory notes with an aggregate principal amount of \$0.925 million and an aggregate amount of accrued interest of \$0.111 million converted to 2.59% of our outstanding membership interests and of the accompanying warrants to purchase 29,629 shares of common stock, 21,620 were exercised within the 30-day exercise period post maturity and the remaining 8,009 were forfeited.

On December 16, 2020, our predecessor entity issued membership interests representing 0.5% of the then outstanding membership interest to Richard Burch and 0.8422% of our then outstanding membership interest to Dr. Pridgen in satisfaction of unpaid but accrued salaries.

On December 16, 2020, immediately after our Corporate Conversion and pursuant to Mr. Burch's employment agreement, Mr. Burch was issued non-qualified stock options to purchase 292,500 shares of our common stock at an exercise price of \$10.00 per share.

The offers, sales and issuances of the securities described above were exempt from registration in reliance upon the exemption from the registration requirements of the Securities Act, as set forth in Section 4(a)(2) under the Securities Act and under Regulation D of the Securities Act, relative to transactions by an issuer not involving a public offering.

Use of Proceeds

On December 21, 2020, we completed our IPO and issued and sold 3,450,000 shares of our common stock (including 450,000 shares of our common stock in connection with the full exercise of the underwriters' option to purchase additional shares) at a price to the public of \$10.00 per share.

There has been no material change in the expected use of the net proceeds from our initial public offering as described in our final prospectus, dated December 16, 2020, filed with the SEC pursuant to Rule 424(b) relating to our registration statement on Form S-1 (Registration No. 333-248447), as amended, filed in connection with our IPO.

Item 6. Selected Financial Data

This item is not required.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

You should read the following discussion and analysis of our financial condition and results of operations in conjunction with the financial statements and the related notes appearing elsewhere in this Form 10-K. This

discussion contains forward-looking statements reflecting our current expectations that involve risks and uncertainties, including those set forth under “Cautionary Statement About Forward-Looking Statements.” Actual results and experience could differ materially from the anticipated results and other expectations expressed in our forward-looking statements as a result of a number of factors, including but not limited to those discussed in this Item and in Item 1A - “Risk Factors.” Actual results and the timing of events could differ materially from those discussed in our forward-looking statements as a result of many factors, including those set forth under “Risk Factors” and elsewhere in this Form 10-K.

Overview

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 FM. Overactive immune response related to activation of tissue resident HSV-1 has been postulated to be a potential root cause of chronic illnesses such as FM, IBS, chronic fatigue syndrome and functional somatic syndrome, all of which are characterized by a waxing and waning manifestation of disease. While not completely understood, there is general agreement in the medical community that activation of HSV-1 is triggered by some form of environmental and/or health stressor. Our lead product, IMC-1, is a novel, proprietary, fixed dose combination of famciclovir and celecoxib. IMC-1 represents a novel combination, dual mechanism, antiviral therapy designed to synergistically suppress HSV-1 activation and replication, with the end goal of reducing viral mediated disease burden.

IMC-1 combines two specific mechanisms of action purposely designed to inhibit HSV-1 activation and replication, thereby keeping HSV-1 in a latent (dormant) state or “down-regulating” HSV-1 from a lytic (active) state back to latency. The famciclovir component of IMC-1 inhibits viral DNA replication. The celecoxib component of IMC-1 inhibits cyclooxygenase-2 (“COX-2”) and to a lesser degree COX-1, enzymes used by HSV-1 to amplify or accelerate its own replication. We are unaware of any other antivirals in development for the treatment of FM specifically used to inhibit both HSV-1 activation and subsequent HSV-1 replication, with the goal of keeping tissue resident HSV-1 tissue in a latent state. This novel approach was a germane consideration in FDA designating IMC-1 for fast-track review status for the treatment of FM. IMC-1 has also been granted a synergy patent based on the fact that neither of the individual components has proven effective in the management of fibromyalgia, yet the dual mechanism combination therapy generated a result that is greater than the sum of its parts.

On December 16, 2020, immediately prior to the effectiveness of our registration statement, we converted into a Delaware corporation pursuant to a statutory conversion, and changed our name from Virios Therapeutics, LLC to Virios Therapeutics, Inc., in what we call the “Corporate Conversion”. As a result of the Corporate Conversion, all of the membership interests held by the existing members of Virios Therapeutics, LLC converted into shares of common stock of Virios Therapeutics, Inc. Prior to the Corporate Conversion, we operated as an Alabama limited liability company.

We have never been profitable and have incurred losses since inception. Our net losses were \$10,346,395 and \$2,473,627 for the years ended December 31, 2020 and 2019, respectively, and our accumulated deficit at December 31, 2020 was \$27,965,105. We expect to incur losses for the foreseeable future, and we expect these losses to increase as we continue to develop and seek regulatory approvals for our product candidate. Because of the numerous risks and uncertainties associated with product development, we are unable to predict the timing or amount of increased expenses or when, or if, we will be able to achieve or maintain profitability.

The development of our drug candidates could be disrupted and materially adversely affected in the future by the COVID-19 pandemic. We are still assessing our business plans and the impact COVID-19 may have on our ability to advance the development of our drug candidates, delays in starting or completing clinical trials, the suspension of clinical trials or to raise financing to support the development of our drug candidates, but no assurances can be given that this analysis will enable us to avoid part or all of any impact

from the spread of COVID-19 or its consequences, including downturns in business sentiment generally or in our sector in particular.

Financial Operations Overview

The following discussion sets forth certain components of our statements of operations as well as factors that impact those items.

Research and Development Expenses

Our research and development expenses consist of expenses incurred in development and clinical studies relating to our product candidate, including:

- payments to third-party contract research organizations, or CROs;
- payments to third-party contract development and manufacturing organizations, or CMOs; and
- payments to contract laboratories and independent consultants.

We expense all research and development costs as incurred, to date all of which have been external. Clinical development expenses for our product candidate is a significant component of our current research and development expenses. Products in later stage clinical development generally have higher research and development expenses than those in earlier stages of development, primarily due to increased size and duration of the clinical trials. We track and record information regarding research and development expenses for each study or trial we conduct. We use third-party CROs, CMOs, contractor laboratories and independent contractors. All research and development costs incurred to date have been external and have been for our lead candidate, IMC-1. We recognize the expenses associated with third parties performing services for us in our clinical studies based on the percentage of each study completed at the end of each reporting period.

Research and development activities are central to our business model. We expect our research and development expenses in 2021 to be higher than in 2020 as a result of increased expenditures for our Phase 2b study in FM. These expenditures are subject to numerous uncertainties regarding timing and cost to completion. Completion of our clinical development and clinical trials may take several years or more. Because of the numerous risks and uncertainties associated with product development, we cannot determine with certainty the duration and completion costs of the current or future studies and clinical trials or if, when, or to what extent we will generate revenues from the commercialization and sale of our product candidates. We may never succeed in achieving regulatory approval for our product candidates. The duration, costs and timing of clinical trials and development of our product candidates will depend on a variety of factors, including:

- successful enrollment in, and completion of, clinical trials;
- successful completion of Investigational New Drug-enabling activities, including for IMC-1 for indications other than FM;
- receipt of marketing approvals from applicable regulatory authorities;
- making arrangements with third-party manufacturers or establishing our own commercial manufacturing capabilities;
- obtaining and maintaining patent and trade secret protection and non-patent exclusivity;
- launching commercial sales of IMC-1, if approved, whether alone or in collaboration with others;

- acceptance of IMC-1, if approved, by patients, the medical community and third-party payors;
- effectively competing with other therapies and treatment options;
- a continued acceptable safety profile following approval;
- enforcing and defending intellectual property and proprietary rights and claims; and
- achieving desirable medicinal properties for the intended indications.

A change in the outcome of any of these factors could mean a significant change in the costs and timing associated with the development of our current and future product candidates. For example, if the FDA, or another regulatory authority were to require us to conduct clinical trials beyond those that we currently anticipate will be required for the completion of clinical development, or if we experience significant delays in execution of or enrollment in any of our clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development. We expect our research and development expenses to increase for the foreseeable future as we continue the development of IMC-1 and other potential product candidates.

General and Administrative Expenses

General and administrative expenses consist primarily of employee-related expenses, including salaries, benefits, and equity and share-based compensation, for personnel in executive, finance, operations and administrative functions. General and administrative expenses also include public company costs, directors and officer's insurance professional fees for legal, including patent related expenses, consulting, auditing and tax services.

We anticipate that our general and administrative expenses will increase in the future to support continued research and development activities and potential commercialization of our product candidates and increased costs of operating as a public company. These increases will likely include increased costs related to the hiring of additional personnel and fees to outside consultants, lawyers and accountants, among other expenses.

Other (Expense) Income, Net

Other (expense) income, net, primarily consists of interest expense on the convertible promissory notes and amortization of related debt issuance costs that converted into membership interests at our Corporate Conversion.

Related Parties

The Company uses Tanner & Guin for general counsel legal services and for other administrative needs. Partners of the law firm are stockholders of the Company.

The Company uses Way, Ray, Shelton & Co., for tax accounting services. A retired partner of the firm is also a stockholder of the Company.

The Company uses Gendreau Consulting, LLC, for drug development, clinical trial design and planning, implementation and execution of contracted activities with CROs. The managing member of the firm is also the Company's CMO effective January 1, 2021. The Company will continue to contract the CMO's spouse as well as an administrative assistant through the firm to perform certain activities in connection with its planned clinical trial in FM.

Upon the completion of the Corporate Conversion, our President, Richard Burch, resigned his position as President and was appointed to our board of directors.

For a full discussion of related party transactions see Note 9 to the Financial Statements included in this Annual Report on Form 10-K.

Income Taxes

The Company has estimated net operating loss carryforwards (“NOLs”) of \$2,315,510 for both Federal income tax purposes and for Georgia income tax purposes as of December 31, 2020. These net operating losses can be carried forward and applied against future taxable income, if any. These losses currently have no expiration date and may be carried forward indefinitely. As the tax year ended December 31, 2020 is the Company’s initial tax year as a C-Corporation, there are no previously filed corporate returns open under statute.

The Company has recorded a full valuation allowance against its net deferred tax assets as of December 31, 2020 and 2019 because the Company has determined that it is more likely than not that these assets will not be fully realized due to historic net operating losses incurred. The ultimate realization of the deferred tax assets is dependent upon the generation of future taxable income during the periods in which these temporary differences become deductible.

Critical Accounting Policies and Use of Estimates

Our management’s discussion and analysis of our financial condition and results of operations is based on our financial statements, which we have prepared in accordance with U.S. generally accepted accounting principles. We believe that several accounting policies are important to understanding our historical and future performance. We refer to these policies as critical because these specific areas generally require us to make judgments and estimates about matters that are uncertain at the time we make the estimate, and different estimates — which also would have been reasonable — could have been used. On an ongoing basis, we evaluate our estimates and judgments, including those described in greater detail below. We base our estimates on historical experience and other market-specific or other relevant assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in the notes to our financial statements appearing elsewhere in this Annual Report on Form 10K, we believe the following accounting policies to be most critical to the judgments and estimates used in the preparation of our financial statements.

Research and Development

Research and development costs are expensed as incurred and are comprised of external research and development expenses incurred under arrangements and contracts with third parties, such as contract research organizations (“CROs”), contract development and manufacturing organizations (“CMOs”) and consultants. As part of the process of preparing its financial statements, the Company may be required to estimate some of its expenses resulting from its obligations under these arrangements and contracts. The financial terms of these contracts are subject to negotiations which vary from contract to contract and may result in payment flows that do not match the periods over which materials or services are provided. The Company’s objective is to reflect the appropriate expenses in its financial statements by matching those expenses with the period in which services are rendered. The Company determines any accrual estimates based on account discussions with applicable personnel and outside service providers as to the progress or state of completion. The Company makes estimates of its accrued expenses as of each balance sheet date based on the facts and circumstances known at that time. The Company’s estimates are dependent upon the timely and accurate reporting of CROs, CMOs and other third-party vendors. At the end of each reporting

period, the Company compares the payments made to each service provider to the estimated progress towards completion of the related project. Factors that the Company considers in preparing these estimates include the number of patients enrolled in studies, milestones achieved, and other criteria related to the efforts of its vendors. These estimates will be subject to change as additional information becomes available. Depending on the timing of payments to vendors and estimated services provided, the Company will record net prepaid or accrued expenses related to these costs.

Equity and Share-Based Compensation

The Company recognizes compensation expense relating to equity-based payments based on the fair value of the equity or liability instrument issued. For equity-based instruments, the expense is based upon the grant date fair value and recognized over the service period. For awards with a performance condition, compensation expense is recognized over the requisite service period if it is probable that the performance condition will be satisfied. For awards to non-employees, the Company recognizes compensation expense in the same manner as if the Company had paid cash for the goods or services. The Company estimates the fair value of options and warrants granted using an options pricing model. Expense is recognized within general and administrative expenses and forfeitures are recognized as they are incurred.

Results of Operations

Operating expenses and other (expense) income were comprised of the following:

	Year Ended December 31,	
	2020	2019
Operating expenses:		
Research and development	\$ 194,013	\$ 800,620
General and administrative	9,811,381	1,377,879
Total operating expenses	\$ 10,005,394	\$ 2,178,499
Other (expense) income:		
Interest expense, net	(384,222)	(295,128)
Other income	43,221	—
Total other expenses	(341,001)	(295,128)
Loss before income taxes	<u>\$ (10,346,395)</u>	<u>\$ (2,473,627)</u>

Years Ended December 31, 2020 and 2019

Research and Development Expenses

Research and development expenses decreased by \$0.6 million or 75.8%, to \$0.2 million for the year ended December 31, 2020 from \$0.8 million for the year ended December 31, 2019. The decrease was primarily due to decreases in expenses for our human PK study conducted in 2019. All of the research and development expenses for the years ended December 31, 2020 and 2019 were external.

General and Administrative Expenses

General and administrative expenses increased by \$8.4 million, or 612.1%, to \$9.8 million for the year ended December 31, 2020 from \$1.4 million for the year ended December 31, 2019. The increase was primarily the result of non-cash expenses related to equity-based compensation of \$2.0 million related to membership interests awarded to our founder and share-based compensation expense of \$5.4 million related to stock options issued pursuant to executive employment agreements upon our IPO. Contributing further to the increase was an increase in expenses for salaries and benefits, legal and accounting fees and other costs

associated with being a public company of \$1.3 million offset by decreases in business development expenses of \$0.3 million.

Other (Expense) Income

Other (expense) income increased by \$0.05 million or 15.5% to \$0.34 million for the year ended December 31, 2020 from \$0.29 million for the year ended December 31, 2019. The increase was primarily due to the increase in interest expense of \$0.09 million related to the issuance of convertible promissory notes in 2020 offset by an increase in other income of \$0.04 million for a vendor concession.

Liquidity and Capital Resources

Since our inception in 2012, we have devoted most of our cash to research and development and general and administrative activities. We have financed our operations primarily with the proceeds from the sale membership interests, convertible promissory notes and with common stock through our recent IPO. To date, we have not generated any revenues from the sale of products, and we do not anticipate generating any revenues from the sales of products for the foreseeable future. We have incurred losses and generated negative cash flows from operations since inception. As of December 31, 2020 our principal source of liquidity was our cash, which totaled \$29.8 million.

The COVID-19 global pandemic has resulted in travel restrictions and temporary shut-downs of non-essential businesses in many states in the U.S. We are able to remain open and all employees work from home. Due to many uncertainties, we are unable to estimate the pandemic's financial impact or duration at this time.

Equity Financings

We closed our IPO on December 21, 2020, raising gross proceeds of \$34.5 million and net proceeds of approximately \$31.1 million, after deducting underwriting discounts, commissions and offering expenses.

Debt Financings

For the years ended December 31, 2020 and 2019, we received net proceeds from the sale of convertible promissory notes of \$1.9 million and \$2.4 million, respectively.

In 2019, we issued an aggregate of \$3.7 million principal amount of convertible promissory notes, \$1.2 million of which were related to the conversion of redeemable preferred convertible interests that were issued in 2018. All of these notes were outstanding for the year ended December 31, 2019. In 2020, we issued an aggregate of \$2.0 million principal amount of convertible promissory notes. At the Corporate Conversion, these notes converted to common interests at the price of \$400,000 per 1% of common interests. There was no debt outstanding for the year ended December 31, 2020.

Non-voting Preferred Members' Interest

In 2018, we sold an aggregate of \$1.3 million of redeemable preferred members' interests. In 2019, \$1.2 million of the redeemable preferred members' interests were converted into convertible promissory notes. The remaining principle of the preferred members' interests of \$0.1 million was repaid upon the closing of our IPO. For the years ended December 31, 2020 and 2019, there were principle amounts outstanding of \$0 and \$0.1 million respectively.

Future Capital Requirements

We estimate our current cash of \$29.8 million at December 31, 2020 is sufficient to fund our operations and capital requirements through the end of 2022. We believe that these available funds will be sufficient to

complete our Phase 2b clinical trial for IMC-1 and commence the planning of our Phase 3 study in FM for this product candidate. However, it is difficult to predict our spending for our product candidate prior to obtaining FDA approval. Moreover, changing circumstances may cause us to expend cash significantly faster than we currently anticipate, and we may need to spend more cash than currently expected because of circumstances beyond our control.

To the extent that our capital resources are insufficient to meet our future operating and capital requirements, we will need to finance our cash needs through public or private equity offerings, debt financings, collaboration and licensing arrangements or other financing alternatives. We have no committed external sources of funds. Additional equity or debt financing or collaboration and licensing arrangements may not be available on acceptable terms, if at all.

Cash Flows

The following table summarizes our cash flows from operating, investing and financing activities.

	Years Ended December 31,	
	2020	2019
Statement of Cash Flows Data:		
Total net cash (used in) provided by:		
Operating activities	\$ (3,895,195)	\$ (2,092,150)
Financing activities	33,381,177	2,371,508
Increase (decrease) in cash	<u>\$ 29,485,982</u>	<u>\$ 279,358</u>

Years ended December 31, 2020 and 2019

Operating Activities

Of the net loss for the year ended December 31, 2020 of \$10.3 million, the net cash used in operating activities was only \$3.9 million with non-cash operating expense items of \$7.4 million offset with a net change in operating assets and liabilities of \$1.0 million. The net change in operating assets and liabilities included an increase in prepaid expenses of \$1.7 million offset by a net increase in operating liabilities of \$0.7 million. Non-cash items consisted primarily of equity and share-based compensation of \$7.4 million. We expect cash used in operating activities to continue to increase in 2021 as compared to 2020 due to an expected increase in our operating losses associated with ongoing development of our product candidate and operating as a public company.

Net cash used in operating activities was \$2.1 million for the year ended December 31, 2019 and consisted of a net loss of \$2.5 million offset by a net change in operating assets and liabilities of \$0.3 million and non-cash items of \$0.1 million. The change in operating assets and liabilities included a net increase in accounts payable and accrued expenses of \$0.3 million. The net increase in accounts payable and accrued expenses is largely due to increases in accrued interest on convertible promissory notes issued in our Fourth Offering and an increase in accrued expenses for incurred but unbilled costs related to our human PK study. Non-cash items consisted of amortization of debt issuance costs of \$0.1 million.

Financing Activities

Net cash provided by financing activities during the year ended December 31, 2020 was \$33.4 million. We received cash proceeds from our IPO of \$31.3 million, net of deal costs and other expenses, \$1.9 million net proceeds from the issuance of convertible promissory notes and \$0.2 million proceeds from the exercise of warrants to purchase our common stock.

Net cash provided by financing activities the year ended December 31, 2019 was \$2.4 million representing the net proceeds from the issuance of convertible promissory notes.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements or relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities.

Recent Accounting Pronouncements

In June 2018, the FASB issued ASU No. 2018-07, *"Compensation Stock Compensation (Topic 718), improvements to Non-Employee Share-Based Payment Accounting."* Under legacy guidance, the accounting for non-employee share-based payments differs from that applied to employee awards, particularly with regard to the measurement date and the impact of performance conditions. ASU 2018-07 provides that existing employee guidance will apply to non-employee share-based transactions (as long as the transaction is not effectively a form of financing), with the exception of specific guidance related to the attributions of compensation cost. The cost of non-employee awards will continue to be recorded as if the grantor had paid cash for the goods or services. In addition, the contractual term will be able to be used in lieu of an expected term in the option-pricing model for non-employee awards. The Company has adopted this standard and applied the application of the new standard to the underwriters warrants.

In December 2019, the FASB issued ASU No. 2019-12, *"Income Taxes (ASC 740): Simplifying the Accounting for Income Taxes."* The standard eliminates the need for an organization to analyze whether the following apply in a given period: (1) the exception to the incremental approach for intraperiod tax allocation; (2) the exceptions to accounting for basis differences when there are ownership changes in foreign investments; and (3) the exception in interim periods income tax accounting for year-to-date losses that exceed anticipated losses. The ASU also is designed to improve financial statement preparers' application of income tax-related guidance and simplify GAAP for (1) franchise taxes that are partially based on income, (2) transactions with a government that result in a step-up in the tax basis of goodwill, (3) separate financial statements of legal entities that are not subject to tax, (4) enacted changes in tax laws in interim periods and (5) certain income tax accounting for employee stock ownership plans and affordable housing projects. The amendments in this Update are effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2020. The Company does not expect adoption to have a material impact on its financial statements.

In August 2020, the FASB issued ASU 2020-06, *"Debt - Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging - Contracts in Entity's Own Equity (Subtopic 815-40)"*. ASU 2020-06 eliminates the beneficial conversion and cash conversion accounting models for convertible instruments. It also amends the accounting for certain contracts in an entity's own equity that are currently accounted for as derivatives because of specific settlement provisions. The new guidance also modifies how particular convertible instruments and certain contracts that may be settled in cash or shares impact the diluted EPS computation. ASU 2020-06 is effective for fiscal years beginning after December 15, 2023, including interim periods within those annual periods. Early adoption is permitted, but no earlier than fiscal years beginning after December 15, 2020, including interim periods within those annual periods. ASU 2020-06 allows companies to adopt the guidance through either a modified retrospective method of transition or a fully retrospective method of transition. The Company is still evaluating the impacts the ASU will have on its financial statements.

JOBS Act

On April 5, 2012, the Jumpstart Our Business Startups Act of 2012, or JOBS Act, was signed into law. The JOBS Act contains provisions that, among other things, reduce certain reporting requirements for an "emerging growth company." As an "emerging growth company," we are electing to take advantage of the

extended transition period afforded by the JOBS Act for the implementation of new or revised accounting standards.

Subject to certain conditions set forth in the JOBS Act, as an “emerging growth company,” we are not required to, among other things, (i) provide an auditor’s attestation report on our system of internal controls over financial reporting pursuant to Section 404, (ii) provide all of the compensation disclosure that may be required of non-emerging growth public companies under the Dodd-Frank Wall Street Reform and Consumer Protection Act, (iii) comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor’s report providing additional information about the audit and the financial statements (auditor discussion and analysis), and (iv) disclose certain executive compensation-related items such as the correlation between executive compensation and performance and comparisons of the chief executive officer’s compensation to median employee compensation. These exemptions will apply until the fifth anniversary of the completion of our initial public offering or until we no longer meet the requirements for being an “emerging growth company,” whichever occurs first.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

This item is not required.

Item 8. Financial Statements and Supplementary Data

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Report of Independent Registered Public Accounting Firm

Shareholders and the Board of Directors
Virios Therapeutics, Inc.

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Virios Therapeutics, Inc. (the "Company") as of December 31, 2020 and 2019, the related statements of operations, members'/stockholders' equity, and cash flows for each of the two years in the period ended December 31, 2020, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2020 and 2019, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2020, in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Dixon Hughes Goodman LLP

We have served as the Company's auditor since 2020.

Atlanta, Georgia
March 23, 2021

VIRIOS THERAPEUTICS, INC.
BALANCE SHEETS

	December 31, 2020	December 31, 2019
Assets		
Current assets:		
Cash	\$ 29,795,366	\$ 309,384
Prepaid expenses and other current assets	1,677,365	6,516
Total current assets	<u>31,472,731</u>	<u>315,900</u>
Total assets	<u>\$ 31,472,731</u>	<u>\$ 315,900</u>
Liabilities and members'/stockholders equity (deficit)		
Current liabilities:		
Accounts payable	\$ 368,905	\$ 35,421
Accrued expenses	784,104	525,445
Accrued salaries	378,833	1,060,000
Total current liabilities	<u>1,531,842</u>	<u>1,620,866</u>
Convertible promissory notes, net	—	3,637,543
Total liabilities	<u>1,531,842</u>	<u>5,258,409</u>
Commitments and contingencies (Note 10)		
Preferred members' interests, non-voting, net	—	75,000
Members' equity (deficit):		
Members' interests, non-voting	—	12,601,201
Stockholders' equity (deficit):		
Common stock, \$0.0001 par value; 43,000,000 shares authorized, 8,305,075 shares issued and outstanding at December 31, 2020 and no shares authorized, no shares issued and outstanding at December 31, 2019	830	—
Preferred stock, \$0.0001 par value; 2,000,000 shares authorized, no shares issued and outstanding at December 31, 2020 and no shares authorized, no shares issued and outstanding at December 31, 2019	—	—
Additional paid-in capital	57,905,164	—
Accumulated deficit	<u>(27,965,105)</u>	<u>(17,618,710)</u>
Total members'/stockholders' equity (deficit)	<u>29,940,889</u>	<u>(5,017,509)</u>
Total liabilities and members'/stockholders' equity (deficit)	<u>\$ 31,472,731</u>	<u>\$ 315,900</u>

See accompanying notes to the financial statements.

**VIROS THERAPEUTICS, INC.
STATEMENTS OF OPERATIONS**

	Year Ended	
	December 31, 2020	December 31, 2019
Revenue	\$ —	\$ —
Operating expenses:		
Research and development	194,013	800,620
General and administrative expenses	9,811,381	1,377,879
Total operating expenses	<u>10,005,394</u>	<u>2,178,499</u>
Loss from operations	<u>(10,005,394)</u>	<u>(2,178,499)</u>
Other (expense) income:		
Interest expense, net	(384,222)	(295,128)
Other income	43,221	—
Total other expense	<u>(341,001)</u>	<u>(295,128)</u>
Loss before income taxes	<u>(10,346,395)</u>	<u>(2,473,627)</u>
Income tax provision (benefit)	<u>—</u>	<u>—</u>
Net loss	<u>\$ (10,346,395)</u>	<u>\$ (2,473,627)</u>
Basic and diluted net loss per share (1)	<u>\$ (2.10)</u>	<u>\$ (0.51)</u>
Weighted average number of shares outstanding – basic and diluted (1)	<u>4,926,985</u>	<u>4,832,494</u>

- (1) The net loss per share and weighted average shares outstanding have been computed to reflect the corporate conversion in Note 1 that occurred on December 16, 2020 prior to the Company's initial public offering (the "IPO"). In conjunction with the IPO all of the Company's members' interest were converted to shares of common stock.

See accompanying notes to the financial statements.

**VIRIOS THERAPEUTICS, INC.
STATEMENTS OF MEMBERS'/STOCKHOLDERS' EQUITY/(DEFICIT)**

	Voting Members' Interests	Non-voting Members' Interests	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Members'/ Stockholders' (Deficit) Equity
			Shares	Par			
Balance, December 31, 2018	\$ —	\$ 12,601,201	—	\$ —	\$ —	\$ (15,145,083)	\$ (2,543,882)
Net loss	—	—	—	—	—	(2,473,627)	(2,473,627)
Balance, December 31, 2019	\$ —	\$ 12,601,201	—	\$ —	\$ —	\$ (17,618,710)	\$ (5,017,509)
Membership conversion to voting interests (2)	12,601,201	(12,601,201)	—	—	—	—	—
Conversion of convertible promissory notes at maturity (2)	2,673,800	—	—	—	—	—	2,673,800
Equity based compensation expense (2)	2,000,000	—	—	—	—	—	2,000,000
Conversion of convertible promissory notes upon corporate conversion (2)	3,434,457	—	—	—	—	—	3,434,457
Equity payment of accrued salaries (2)	536,880	—	—	—	—	—	536,880
Corporate conversion at initial public offering	(21,246,338)	—	4,832,494	483	21,245,855	—	—
Issuance of common shares for IPO, net of costs	—	—	3,450,000	345	31,053,543	—	31,053,888
Share-based compensation expense	—	—	—	—	5,429,518	—	5,429,518
Exercise of warrants	—	—	22,581	2	176,248	—	176,250
Net loss	—	—	—	—	—	(10,346,395)	(10,346,395)
Balance, December 31, 2020	\$ —	\$ —	8,305,075	\$ 830	\$ 57,905,164	\$ (27,965,105)	\$ 29,940,889

(2) These transactions occurred prior to the corporate conversion.

See accompanying notes to the financial statements.

**VIRIOS THERAPEUTICS, INC.
STATEMENTS OF CASH FLOWS**

	Year Ended	
	December 31, 2020	December 31, 2019
Cash flows from operating activities		
Net loss	\$ (10,346,395)	\$ (2,473,627)
Adjustments to reconcile net loss to net cash used in operating activities:		
Amortization of issuance costs	53,983	62,841
(Recovery)/provision for uncollectable receivables	(15,020)	2,160
Gain on vendor concession	(43,221)	
Equity and share-based compensation expense	7,429,518	—
Changes in operating assets and liabilities:		
(Increase) decrease:		
Prepaid expenses and other current assets	(1,655,829)	3,696
Accounts payable	51,560	(89,824)
Accrued expenses	774,496	348,854
Accrued salaries	(144,287)	53,750
Net cash used in operating activities	<u>(3,895,195)</u>	<u>(2,092,150)</u>
Cash flows from financing activities		
Proceeds from initial public offering, net of costs	31,349,055	—
Proceeds from issuance of convertible promissory notes	1,994,133	2,430,000
Proceeds from the exercise of warrants	176,250	—
Payment of issuance costs for promissory notes	(63,261)	(58,492)
Payment of preferred members' interest	(75,000)	—
Net cash provided by financing activities	<u>33,381,177</u>	<u>2,371,508</u>
Net increase in cash	29,485,982	279,358
Cash, beginning of period	309,384	30,026
Cash, end of period	\$ 29,795,366	\$ 309,384
Supplemental disclosure of non-cash financing transactions:		
Cash paid for interest	\$ 12,551	\$ —
Non-cash financing transactions:		
Accrued deferred issuance costs	\$ —	\$ 5,290
Public offering costs included in accounts payable and accrued expenses	\$ 295,166	\$ —
Conversion of members' interest into common stock at corporate conversion	\$ 21,246,338	\$ —
Conversion of non-voting members' interest to voting members' interest	\$ 12,601,201	\$ —
Payment of accrued salaries through issuance of members' interest	\$ 536,880	\$ —
Conversion of convertible promissory notes and accrued interest into membership interests, net of unamortized deferred costs of \$41,445	\$ 6,108,257	\$ —
Conversion of non-voting preferred members' interests to convertible promissory notes	\$ —	\$ 1,245,000

See accompanying notes to the financial statements.

**VIRIOS THERAPEUTICS, INC.
NOTES TO FINANCIAL STATEMENTS**

1. Background and Organization

Virios Therapeutics, Inc. (the "Company") was incorporated under the laws of the State of Delaware on December 16, 2020 through a corporate conversion (the "Corporate Conversion") just prior to the Company's initial public offering ("IPO"). The Company a.k.a. Virios Therapeutics, LLC and before that, Innovative Med Concepts, LLC, was originally formed as a limited liability corporation ("LLC") under the laws of the State of Alabama on February 28, 2012. On July 23, 2020, the Company changed its name from Innovative Med Concepts, LLC to Virios Therapeutics, LLC.

The Company operates in one segment as a pre-revenue, clinical-stage biotechnology company focused on advancing novel antiviral therapies to treat diseases associated with a viral triggered abnormal immune response. The Company is developing its initial product, IMC-1, for people who are suffering from fibromyalgia. Research has shown that Herpes Simplex Virus-1 ("HSV-1") could be a root cause of fibromyalgia. IMC-1 is a novel, proprietary, fixed dose combination of famciclovir and celecoxib, both of which are approved FDA drugs for other indications. IMC-1 combines these two specific mechanisms of action purposely designed to inhibit HSV-1 activation and replication, thereby keeping HSV-1 in a latent or dormant state. The famciclovir component of IMC-1 inhibits viral DNA replication, thus inhibiting upregulation of the HSV-1 virus. The celecoxib component of IMC-1 inhibits cyclooxygenase-2 ("COX-2") enzymes used by HSV-1 to amplify or accelerate its own replication. IMC-1's synergistic antiviral mechanism represents a first-in-class medicine designed specifically to inhibit both HSV-1 activation and subsequent HSV-1 replication, with the goal of keeping tissue resident HSV-1 tissue in a latent state.

Corporate Conversion

On December 16, 2020, immediately prior to the effectiveness of the Company's registration statement, the Company converted into a Delaware corporation pursuant to a statutory conversion, and changed its name to from Virios Therapeutics, LLC to Virios Therapeutics, Inc., the "Corporate Conversion". As a result of the Corporate Conversion, all of the membership interests held by the existing members of Virios Therapeutics, LLC converted into shares of common stock of Virios Therapeutics, Inc. The purpose of the Corporate Conversion was to reorganize the corporate structure so that the entity offering common stock to the public was a corporation rather than a limited liability company.

Initial Public Offering

On December 16, 2020, the Company announced the pricing of its initial public offering (the "IPO") of 3,000,000 shares of its common stock at an initial offering price of \$10.00 per share. In addition, the Company granted the underwriters a 45-day option to purchase up to an additional 450,000 shares of common stock at the public offering price. The Company's common stock commenced trading on the Nasdaq Capital Markets Exchange on December 17, 2020 under the ticker symbol "VIRI". The IPO closed on December 21, 2020 at which time the underwriters exercised their option to purchase 450,000 additional shares of the Company's common stock bringing the total number of shares of common stock sold by the Company to 3,450,000 shares. The gross proceeds from the IPO, including proceeds from the exercise of the underwriters' option to purchase additional shares, were \$34.5 million. The net proceeds of the IPO were approximately \$31.1 million after deducting underwriting discounts, commissions and offering expenses payable by the Company, including offering costs accrued and unpaid as of December 31, 2020. In conjunction with the IPO, the Company granted the underwriters 172,500 warrants to purchase shares of Company common stock at an exercise price of \$12.50 per share, which is 125% of initial public offering price.

Material Uncertainty

Since its founding, the Company has been engaged in organizational activities, including raising capital, and research and development activities. The Company has not generated any revenues to date. As such, the Company is subject to all of the risks associated with any clinical-stage biotechnology company that has substantial expenditures for research and development. Since inception, the Company has incurred losses and negative cash flows from operating activities. The Company does not expect to generate positive cash flows from operating activities in the near future.

For the years ended December 31, 2020 and 2019, the Company incurred net losses of \$10,346,395 and \$2,473,627, respectively, and had net cash flows used in operating activities of \$3,895,195 and \$2,092,150, respectively. As of December 31, 2020, the Company had an accumulated deficit of approximately \$28.0 million and is expected to incur losses in the future as it continues its development activities. Since its inception, the Company has funded its losses primarily through issuance of members' interests, convertible debt instruments and issuance of equity securities.

As of the date these financial statements are issued, management believes that the net proceeds from the Company's IPO and the current cash are sufficient to fund operations and capital requirements for at least the next 12 months. The Company will need to raise additional capital to complete clinical development of and to commercially develop its product candidates. There is no assurance that such financing will be available when needed or on acceptable terms. The financial statements do not include any adjustments to reflect this uncertainty.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying financial statements have been prepared in conformity with U.S. generally accepted accounting principles ("U.S. GAAP"). Any reference in these notes to applicable guidance is meant to refer to U.S. GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Update ("ASU") of the Financial Accounting Standards Board ("FASB").

Use of Estimates

The preparation of these financial statements and accompanying notes in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting

period. The Company's significant estimates and assumptions include estimated work performed but not yet billed by contract manufacturers, engineers and research organizations, the valuation of equity and stock-based related instruments, and the valuation allowance related to deferred taxes. Some of these judgments can be subjective and complex, and, consequently, actual results could differ from those estimates. Although the Company believes that its estimates and assumptions are reasonable, they are based upon information available at the time the estimates and assumptions were made. Actual results could differ from those estimates.

Segment Information

The Company operates in one reportable segment based on management's view of its business for purposes of evaluating performance and making operating decisions.

Concentrations of Credit Risk

Cash and cash equivalents are financial instruments that are potentially subject to concentrations of credit risk. The Company believes it is not exposed to significant credit risk due to the financial strength of the depository institutions in which the cash is held.

Fair Value Measurements

ASC Topic 820, *Fair Value Measurement*, provides guidance on the development and disclosure of fair value measurements. Under this accounting guidance, fair value is defined as an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or a liability.

The accounting guidance classifies fair value measurements in one of the following three categories for disclosure purposes:

- Level 1 — Quoted prices in active markets for identical assets or liabilities.
- Level 2 — Inputs other than Level 1 prices for similar assets or liabilities that are directly or indirectly observable in the marketplace.
- Level 3 — Unobservable inputs which are supported by little or no market activity and values determined using pricing models, discounted cash flow methodologies, or similar techniques, as well as instruments for which the determination of fair value requires significant judgment or estimation.

The carrying amount of the Company's financial instruments, including cash, accounts payable and accrued expenses approximate their fair values.

Cash

Cash is maintained in bank deposit accounts, which exceed the federally insured limits of \$250,000. The Company does not have any cash equivalents.

Variable Interest Entities

When determining whether a legal entity should be consolidated, the Company first determines whether it has a variable interest in the legal entity. If a variable interest exists, the Company determines whether the legal entity is a variable interest entity ("VIE") due to either: 1) a lack of sufficient equity to finance its activities, 2) its equity holders lacking the characteristics of a controlling financial interest, or 3) the legal entity

being structured with non-substantive voting rights. If the Company concludes that the legal entity is a VIE, the Company next determines whether it is the primary beneficiary due to it possessing both: 1) the power to direct the activities of a VIE that most significantly impact the VIE's economic performance, and 2) the obligation to absorb losses of the VIE that potentially could be significant to the VIE or the right to receive benefits from the VIE which could be significant to the VIE. If the Company concludes that it is the primary beneficiary, it consolidates the entity.

Equity Method Investment

In 2017, the Company purchased a 25% ownership in Northriver Pharm, LLC ("NRP") in the amount of \$125,000 from existing investors of NRP. NRP is an entity with common ownership with the Company's former Chief Executive Officer and Founder, who is also the Founder and sole voting member of NRP. The Company evaluated the ownership under VIE guidance and has determined that they do not have the power and economics to control the entity and are not the entity most closely associated with NRP.

The Company previously accounted for the investment under the equity method of accounting. However, consistent with equity method accounting guidance, the Company has now discontinued applying the equity method accounting as the investment has been reduced to zero and the Company has not committed to provide further financial support and there is no expected return to profitable operations by NRP.

Deferred Issuance Costs

Deferred issuance costs are netted against amounts outstanding for the convertible promissory notes or mezzanine preferred members' interests when the offering is completed. Expenditures incurred prior to the closing are capitalized as deferred issuance costs in non-current assets. There were no amounts capitalized prior to an offering as of December 31, 2020 and 2019.

Upon closing, capitalized costs relating to debt offering are recognized into interest expense over the terms of the instruments using the effective interest method. The Company recognized interest expense related to the amortization of issuance costs for the convertible promissory notes and the mezzanine preferred members' interests as follows:

	December 31, 2020	December 31, 2019
Convertible promissory notes	\$ 53,983	\$ 26,325
Mezzanine preferred members' interests	—	36,516
	<u>\$ 53,983</u>	<u>\$ 62,841</u>

Accrued Salaries

Accrued salaries represent outstanding guaranteed payments to the Company's former President and former Chief Executive Officer and Founder and are recognized when incurred and considered payable.

Income Taxes

The Company provides for income taxes using the asset and liability approach. Deferred tax assets and liabilities are recorded based on the differences between the financial statement and tax bases of assets and liabilities and the tax rates in effect when these differences are expected to reverse. Deferred tax assets are reduced by a valuation allowance if, based on the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized. The Company operated as an Alabama limited liability company until its Corporate Conversion. Therefore, the Company passed through all income and losses to its members until this point. As of December 31, 2020, the Company had a full valuation allowance against deferred tax assets.

The Company is subject to the provisions of ASC 740, *Income Taxes*. Under ASC 740, consideration is given to the recognition and measurement of tax positions that meet a “more-likely-than-not” threshold. A tax position is a position taken in a previously filed tax return or a position expected to be taken in a future that is reflected in measuring current or deferred income tax assets and liabilities. Tax positions include the Company’s status as a pass-through entity until December 16, 2020 and as a corporation thereafter. The recognition and measurement of tax positions taken for various jurisdictions consider the amounts and probabilities of outcomes that could be realized upon settlement using the facts, circumstances, and information available at the reporting date. The Company has determined that it does not have any material unrecognized tax benefits or obligations as of December 31, 2020 and 2019. The Company recognizes interest and penalties related to uncertain tax positions, if any, in income tax expense. The Company is not currently under examination by the Internal Revenue Service or by state tax authorities and the Company’s tax year remains subject to examination by the tax authorities.

Basic and Diluted Net Income (Loss) per Share

Basic net loss per common share (“EPS”) is computed in accordance with U.S. GAAP. Basic EPS is computed by dividing net loss by the weighted average number of common shares outstanding during the period. Diluted EPS reflects potential dilution and is computed by dividing net loss by the weighted average number of common shares outstanding during the period increased by the number of additional common shares that would have been outstanding if all potential common shares had been issued and were dilutive. However, potentially dilutive securities are excluded from the computation of diluted EPS to the extent that their effect is anti-dilutive. For the year ended December 31, 2020, the Company had 811,663 options and 276,583 warrants to purchase common shares outstanding that were anti-dilutive. There were no anti-dilutive securities outstanding for the year ended December 31, 2019.

EPS and weighted-average shares outstanding have been computed to give effect to the Corporate Conversion that occurred December 16, 2020 prior to the Company’s initial public offering. In conjunction with the Corporate Conversion, all of the Company’s outstanding members’ equity automatically converted into shares of common stock, based on the relative rights of the Company’s pre-IPO equityholders.

Research and Development

Research and development costs are expensed as incurred. All research and development costs incurred to date have been external and have been for our lead candidate, IMC-1. The Company arranges and contracts with third-party contract research organizations (“CROs”), contract development and manufacturing organizations (“CMOs”), contractor laboratories and independent consultants. As part of the process of preparing its financial statements, the Company may be required to estimate some of its expenses resulting from its obligations under these arrangements and contracts. The financial terms of these contracts are subject to negotiations which vary from contract to contract and may result in payment flows that do not match the periods over which materials or services are provided. The Company’s objective is to reflect the appropriate expenses in its financial statements by matching those expenses with the period in which services are rendered. The Company determines any accrual estimates based on account discussions with applicable personnel and outside service providers as to the progress or state of completion. The Company makes estimates of its accrued expenses as of each balance sheet date based on the facts and circumstances known at that time. The Company’s estimates are dependent upon the timely and accurate reporting of CROs, CMOs and other third-party vendors. At the end of each reporting period, the Company compares the payments made to each service provider to the estimated progress towards completion of the related project. Factors that the Company considers in preparing these estimates include the number of patients enrolled in studies, milestones achieved, and other criteria related to the efforts of its vendors. These estimates will be subject to change as additional information becomes available. Depending on the timing of payments to vendors and estimated services provided, the Company will record net prepaid or accrued expenses related to these costs.

Equity and Share-Based Compensation

The Company recognizes compensation expense relating to equity-based payments based on the fair value of the equity or liability instrument issued. For equity-based instruments, the expense is based upon the grant date fair value and recognized over the service period. For awards with a performance condition, compensation expense is recognized over the requisite service period if it is probable that the performance condition will be satisfied. For awards to non-employees, the Company recognizes compensation expense in the same manner as if the Company had paid cash for the goods or services. The Company estimates the fair value of options and warrants granted using an options pricing model, see Note 11. Expense is recognized within general and administrative expenses and forfeitures are recognized as they are incurred.

Emerging Growth Company Status

The Company is an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. The Company has elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date that is (i) no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition period provided by the JOBS Act. As a result, these financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates.

Recent Accounting Pronouncements

In June 2018, the FASB issued ASU No. 2018-07, *“Compensation Stock Compensation (Topic 718), improvements to Non-Employee Share-Based Payment Accounting.”* Under legacy guidance, the accounting for non-employee share-based payments differs from that applied to employee awards, particularly with regard to the measurement date and the impact of performance conditions. ASU 2018-07 provides that existing employee guidance will apply to non-employee share-based transactions (as long as the transaction is not effectively a form of financing), with the exception of specific guidance related to the attributions of compensation cost. The cost of non-employee awards will continue to be recorded as if the grantor had paid cash for the goods or services. In addition, the contractual term will be able to be used in lieu of an expected term in the option-pricing model for non-employee awards. The Company adopted the standard as of and applied the application of the new standard to the underwriters warrants in Note 11.

In December 2019, the FASB issued ASU No. 2019-12, *“Income Taxes (ASC 740): Simplifying the Accounting for Income Taxes.”* The standard eliminates the need for an organization to analyze whether the following apply in a given period: (1) the exception to the incremental approach for intraperiod tax allocation; (2) the exceptions to accounting for basis differences when there are ownership changes in foreign investments; and (3) the exception in interim periods income tax accounting for year-to-date losses that exceed anticipated losses. The ASU also is designed to improve financial statement preparers’ application of income tax-related guidance and simplify GAAP for (1) franchise taxes that are partially based on income, (2) transactions with a government that result in a step-up in the tax basis of goodwill, (3) separate financial statements of legal entities that are not subject to tax, (4) enacted changes in tax laws in interim periods and (5) certain income tax accounting for employee stock ownership plans and affordable housing projects. The amendments in this Update are effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2020. The Company does not expect adoption to have a material impact on its financial statements.

In August 2020, the FASB issued ASU 2020-06, *“Debt - Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging - Contracts in Entity’s Own Equity (Subtopic 815-40)”*. ASU 2020-06 eliminates the beneficial conversion and cash conversion accounting models for convertible instruments. It also amends the accounting for certain contracts in an entity’s own equity that are currently

accounted for as derivatives because of specific settlement provisions. The new guidance also modifies how particular convertible instruments and certain contracts that may be settled in cash or shares impact the diluted EPS computation. ASU 2020-06 is effective for fiscal years beginning after December 15, 2023, including interim periods within those annual periods. Early adoption is permitted, but no earlier than fiscal years beginning after December 15, 2020, including interim periods within those annual periods. ASU 2020-06 allows companies to adopt the guidance through either a modified retrospective method of transition or a fully retrospective method of transition. The Company is still evaluating the impacts the ASU will have on its financial statements.

Reclassifications

In certain instances, amounts reported in prior period financial statements have been reclassified from research and development expenses to general and administrative expenses to conform to the current financial statement presentation. Such reclassifications had an effect on previously reported expenses on the statement of operations of \$35,555 for the year ended December 31, 2019.

3. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist of the following:

	December 31, 2020	December 31, 2019
Prepaid insurance	\$ 1,586,042	\$ —
Prepaid CRO costs	85,270	—
Prepaid data room hosting services	5,729	5,731
Miscellaneous receivables	324	785
Total prepaid expenses and other assets	\$ 1,677,365	\$ 6,516

4. License Agreement

The Company entered into a Know-How License Agreement (the "Agreement") with the University of Alabama ("UA") in 2012. In consideration for the Agreement, UA received a 10% non-voting membership interest in the Company. Upon the adoption of the May 1, 2020 Second Amended and Restated Operating Agreement, the non-voting membership interest converted to a voting membership interest as discussed in Note 7 below. Upon the Corporate Conversion, voting membership interest was converted into shares of common stock. The Agreement is in effect for 25 years and will terminate on June 1, 2037.

5. Accrued Expenses

Accrued expenses consist of the following:

	December 31, 2020	December 31, 2019
Accrued compensation	\$ 573,479	\$ —
Accrued interest on preferred members' interests	188,085	188,085
Accrued interest on promissory notes	—	163,123
Accrued CRO and CMO costs	—	149,178
Other	22,540	25,059
	\$ 784,104	\$ 525,445

6. Convertible Promissory Notes, Net

On March 31, 2020, the Company completed and closed its first round of its fifth offering (the "Fifth Offering") subscription for the issuance of convertible promissory notes (collectively with the promissory notes of the Fourth Offering, the "Notes") for convertible preferred membership interests (collectively with the convertible preferred membership interests from the Fourth Offering, the "Convertible Interests"). The Company received \$1,162,500 worth of subscriptions. On June 10, 2020, the Company completed and closed its second round of its Fifth Offering having received \$706,633 worth of subscriptions. On August 21, 2020, the Company completed and closed its third round of its Fifth Offering having received \$125,000 worth of subscriptions. The terms of both the First Round and Second Round were substantially identical to those of the Third Round, except that the Third Round allowed the investors to convert the cash interest component into additional equity.

Such option was given to the investors in the First Round and Second Round through a separate Interest Conversion Agreement. The same conversion option was given to all of the investors in all rounds of the Fourth Offering. The Company accounted for the changes in accordance with debt modification guidance under ASC 470 "Debt" and determined that the cash flows did not change as a result of the modifications.

The Fifth Offering was considered to be on a *pari passu* basis with the Fourth Offering, discussed below, such that all subscriptions received were considered part of one offering, not diluting the interests issued in the Fourth Offering, regardless of the date of conversion of interests granted in the Fourth offering or the Fifth Offering.

During 2019, the Company completed and closed its fourth offering (the "Fourth Offering") subscription for the issuance of convertible promissory notes for convertible preferred membership interests. The Fourth Offering consisted of three rounds. The first round completed and closed on January 18, 2019, having received \$925,000 worth of subscriptions. The second round completed and closed on May 31, 2019, having received another \$925,000 worth of subscriptions. The third round completed and closed on November 30, 2019, having received \$580,000 worth of subscriptions.

The Notes bore interest at 8% per annum, with a maximum term of 18 months. If investors executed an Interest Conversion Agreement, as discussed above, or if part of the third round of the Fifth Offering, then any accrued interest converted into common membership interests ("Common Interests") at maturity, otherwise the accrued interest was paid in cash. Per the original terms of the Notes, the principal portion of the instrument was only payable through conversion into Common Interests of the Company upon the earlier of (i) the completion of an equity raise sufficient to fund the Company's Phase IIb or Phase III, or (ii) 18 months from the closing date of each round. The Company recognized interest expense related to the Notes as follows:

	December 31, 2020	December 31, 2019
Fourth Offering	\$ 231,364	\$ 163,123
Fifth Offering	98,634	—
	<u>\$ 329,998</u>	<u>\$ 163,123</u>

Also per the original terms of the Notes, the Convertible Interests were to convert to Common Interests that resulted in the greater ownership percentage of the price issued in connection with the next equity raise sufficient to fund the Company's Phase IIb or Phase III, or at the price of \$400,000 per 1% of Common Interests. If no equity raise was completed within the 18-month term, the Convertible Interests automatically converted into Common Interests at the price of \$400,000 per 1% of Common Interests.

The Company determined the conversion feature of the Notes did not require bifurcation as the embedded conversion option required physical cash settlement and did not provide for net settlement.

Further, the Company determined that the conversion feature of the Notes were not in the money at issuance and thereby did not represent a beneficial conversion feature.

In addition, each Convertible Interest included warrant coverage of 25% of the principal value of the Note, which provided an option to purchase additional Common Interests in cash at the same price as the conversion of the Note. The warrant coverage was exercisable on the conversion date, or within 30 days post conversion. If not exercised within this 30 day period the warrant coverage was forfeited.

The warrant coverage was evaluated to determine whether the arrangements were embedded or free-standing (i.e., to determine whether they needed to be bifurcated and accounted for as a separate financial instrument). However, since the warrants were only exercisable at the time of conversion or within 30 days post conversion of the Convertible Interests, and there were restrictions on transfer, they were considered to be non-detachable and did not require to be accounted for separately from the hybrid instrument.

The Notes were unsecured obligations and did not contain any financial covenants or restrictions on the payments to members, the incurrence of indebtedness, or the issuance or repurchase of securities by the Company.

In connection with the Fourth Offering, investors who acquired Preferred Membership Interests in the Third Offering (Note 7), were offered an option to convert the principal of their Preferred Membership Interests into Convertible Interests. In the first and third round of the Fourth Offering, \$540,000 and \$705,000, respectively, of Preferred Membership Interests were converted into Convertible Interests.

On July 20, 2020 the first round of the Fourth Offering Notes matured. As a result, the outstanding principle amount of \$1,465,000 plus accrued interest of \$172,800 converted into membership interests based on the carrying value of the convertible debt with no gain or loss recognized. Accrued interest of \$3,000 was paid in cash. None of the outstanding warrants of \$366,250 were exercised within the 30-day exercise period post maturity and thus were forfeited.

On November 30, 2020 the second round of the Fourth Offering Notes matured. As a result, the outstanding principle amount of \$925,000 plus accrued interest of \$111,000 converted into membership interests based on the carrying value of the convertible debt with no gain or loss recognized. No accrued interest was paid in cash. At the Corporate Conversion outstanding warrants of \$231,250 were converted into 29,629 exercisable warrants of the Company's common stock, of which 21,620 warrants were exercised within the 30-day exercise period post maturity and the remaining 8,009 were forfeited.

At the Corporate Conversion, the third round of the Fourth Offering Notes and all rounds of the Fifth Offering Notes matured. As a result, the aggregate outstanding principle amount of \$3,279,133 plus accrued interest through the conversion date of December 16, 2020 of \$196,769 converted into memberships interests based on the carrying value of the convertible debt, net of unamortized deferred offering costs of \$41,445 with no gain or loss recognized. Accrued interest of \$9,551 was paid in cash. Warrants totaling \$820,033 were converted into 105,044 exercisable warrants of the Company's common stock, of which 961 warrants were exercised and 104,083 were outstanding as of December 31, 2020. See Note 13 for further information of the exercise and expiration of these remaining warrants subsequent to 2020.

7. Members' Equity (Deficit)

On May 1, 2020, the Company adopted its Second Amended and Restated Operating Agreement (the "Amended Operating Agreement"). The Amended Operating Agreement changed the Company's classes of membership from two classes (voting and non-voting) to one class of membership and gave the Board the rights to make all decisions concerning the business, affairs and properties of the Company. Under the Amended Operating Agreement, the members have the right to vote on the dissolution and termination of the Company, the removal of existing directors, the appointment of new directors, and any amendment to the

LLC Agreement itself, which would include any plan of conversion or merger into a different form of legal entity. As such, all members have the same rights, privileges and powers and are considered as voting members' interests in the accompanying balance sheet and statement of members' interest/members' deficit.

At December 31, 2019, the Company was authorized to issue two classes of membership interests, voting and non-voting. Dr. William Pridgen, the Founder, held the only voting membership interest of the Company. There was no value assigned to voting membership interest on the balance sheet as of December 31, 2019, as the Founder's membership interest was granted for contributed patents that were not assigned a value under U.S. GAAP.

On July 17, 2020, the Company's board approved a 0.5% membership interest bonus to be issued to Dr. Pridgen in recognition of his efforts in helping the Company raise capital during its Fifth Offering. In addition, the Company's operating agreement provides for a 4.5% membership interest to be issued to Dr. Pridgen upon a successful sale or license of the Company's patents. On August 19, 2020, the Company's Board approved the issuance of a 4.5% membership interest to Dr. Pridgen to preserve the intent originally set forth in the Company's operating agreement. These issuances were considered equity-based compensation award grants that do not have any future service conditions. As a result, all compensation expense was recognized upon issuance. In order to determine the amount of compensation expense to record, the Company leveraged recent observable prices under the terms of its Fifth Offering. For the year ended December 31, 2020, the Company recognized \$2,000,000 of compensation expense for these issuances.

In conjunction with the Corporate Conversion, all of the Company's outstanding membership interests converted into shares of common stock.

Preferred Members' Interest, Net

From January 2018 through August 2018, the Company entered into its third offering (the "Third Offering") to sell non-voting preferred membership interests ("Preferred Membership Interests") at the price of \$1,000,000 per 1% of membership interest in the Company. The Company raised a total of \$1,320,000, less issuance costs of \$69,532, in its Third Offering.

The Preferred Membership Interests bore interest at 12% per annum, with a cap on total interest earned of 18%. Interest was guaranteed to each investor from the date of investment until the earlier of (i) the sale or exchange of the Company, (ii) 18 months, or (iii) the raising of sufficient funds to complete a Phase III trial. Interest has accumulated and will be paid upon the earlier of the sale or exchange of the Company. The Principal will be repaid upon the earlier of the Company raising funds to complete a Phase III trial or either a sale or exchange of the Company. The Preferred Membership Interests participate in any profits or losses identically as with the other existing membership interests, except that the maximum total return on a Preferred Membership Interest shall be 300% of the original investment. There was no interest expense recognized during the year ended December 31, 2020. The Company recognized \$68,828 of interest expense for the year ended December 31, 2019, relating to the Preferred Membership Interests.

Pursuant to the terms of the Third Offering Subscription Agreement, the principal portion of the investment is to be repaid upon the earlier of (i) the Company raising funds to complete a Phase III trial or (ii) either a sale or exchange of the Company (for avoidance of doubt, raising of funds through an initial public offering shall be considered raising sufficient funds to complete a Phase III trial, but not a sale or exchange of the Company). As the Company closed its IPO on December 21, 2020, raising funds sufficient to complete a Phase III trial, the outstanding principal portion of \$75,000 was repaid to the holders of the Preferred Membership Interests. As shown in Note 5, the accrued interest remains unpaid as neither triggering event for payment has occurred as of December 31, 2020.

For the year ended December 31, 2019, the Preferred Membership Interests are recorded as mezzanine equity, net of issuance cost, on the balance sheet because they are redeemable upon a change in control.

The Company did not believe a change in control is considered probable until it occurs and other contingent events requiring redemption are in control of the Company.

In 2019, in connection with the Fourth Offering, Preferred Membership interest holders were provided an opportunity to convert their ownership into Convertible Promissory Notes. \$1,245,000 of the Preferred Membership Interests were converted into Convertible Interests in connection with the Fourth Offering (Note 6). The Company reclassified the securities from equity to liabilities at the fair value as of the date of the reclassification, recognizing no gain or loss.

8. Stockholders' Equity (Deficit)

The Company's certificate of incorporation adopted on December 16, 2020, authorizes the issuance of two classes of stock to be designated, respectively, "Common Stock" and "Preferred Stock". The total number of shares which the Company is authorized to issue is 45,000,000, each with a par value of \$0.0001 per share. Of these shares, 43,000,000 shall be Common Stock and 2,000,000 shall be Preferred Stock.

Common Stock

Dividends

Subject to the rights of holders of all classes of Company stock outstanding having rights that are senior to or equivalent to holders of the Common Stock are entitled to receive dividends when and as declared by the Board.

Liquidation

Subject to the rights of holders of all classes of stock outstanding having rights that are senior to or equivalent to the holders of Common Stock as to liquidation, upon liquidation, dissolution or winding up of the Company, the assets of the Company will be distributed to the holders of the Common Stock.

Voting

The holders of the Common Stock are entitled to one vote for each share of Common Stock held. There is no cumulative voting.

Preferred Stock

Preferred Stock may be issued from time to time by the Board in one or more series.

9. Related Parties

The Company uses Tanner & Guin, a law firm, for general counsel legal services and for administrative needs in connection with the Company's offerings. As of December 31, 2020, partners of the law firm are stockholders of the Company and as of December 31, 2019 these partners were non-voting members as well as convertible promissory note holders of the Company. The Company paid the firm \$349,107 and \$217,129 during 2020 and 2019, respectively, and had accounts payable of \$30,645 and \$14,150 to the firm as of December 31, 2020 and 2019, respectively.

The Company uses Way, Ray, Shelton & Co., an accounting firm, for tax accounting services. As of December 31, 2020, a retired partner of the accounting firm is a stockholder of the Company and as of December 31, 2019, the partner was a non-voting member as well as a convertible promissory note holder of the Company. The Company paid the firm \$22,100 and \$19,098 during 2020 and 2019, respectively, and had accounts payable of \$12,826 and \$0 to the firm as of December 31, 2020 and 2019, respectively.

The Company uses Create Group, NYC, an advertising agency, for website and presentation design and development. The Director of Account Services is the Company's former President's daughter. The Company paid the firm \$23,059 during 2020.

The Company uses Gendreau Consulting, LLC, a consulting firm, for drug development, clinical trial design, and planning, implementation and execution of contracted activities with CROs. The managing member of the firm is also the Company's CMO effective January 1, 2021. The Company will continue to contract the services of the CMO's spouse through the firm to perform certain activities in connect with its upcoming clinical trial in FM. The Company paid the firm \$450 and \$18,467 during 2020 and 2019, respectively, and had accounts payable of \$7,916 and \$0 to the firm as of December 31, 2020 and 2019, respectively.

In addition to the Company's investment for ownership interest in NRP, the Company paid certain legal and administrative costs for the benefit of NRP of \$100 and \$2,160 during 2020 and 2019, respectively. When the payments were made, the Company recognized a receivable on its balance sheet within other current assets for the total amounts paid. Management had previously determined the collectability of this receivable was not probable, thus fully reserving for the outstanding receivable and recognizing a bad debt expense for any additions to the receivable balance during the periods. In May 2020, the Company reached a settlement with the Manager of NRP who is the former Company CEO and Founder, whereby the outstanding receivable balance of \$20,161 due to the Company at that time by NRP would be settled by his personal contribution of 75% of the amount owed, or \$15,120, by way of reduction in the amount owed to him by the Company. The remaining 25% or \$5,041 was deemed a capital contribution to NRP by the Company to maintain its 25% ownership in NRP and was simultaneously written off against the reserve for uncollectible accounts. For the year ended December 31, 2020, the Company recognized a net recovery of bad debt expense in the amount of \$15,020. For the year ended December 31, 2019, the Company recognized bad debt expense in the amount of \$2,160. The receivable due from NRP was \$0 and \$20,061 as of December 31, 2020 and December 31, 2019, respectively.

10. Commitments and Contingencies

Litigation

The Company is subject, from time to time, to claims by third parties under various legal disputes. The defense of such claims, or any adverse outcome relating to any such claims, could have a material adverse effect on the Company's liquidity, financial condition and cash flows. At December 31, 2020 and 2019, the Company did not have any pending legal actions.

Employment Agreement and Deferred Compensation Plan

In April 2020, the Company entered into three employment agreements with its new CEO, VP of Operations and VP of Finance (the "Executives"), effective April 5, 2020. Per the terms of the agreements and upon the establishment of a bonus program approved by the Board, each Executive is entitled to receive a cash bonus with a target amount of no less than 50% for the CEO and 20% for the VP of Operations and the VP of Finance of the then-current base salary. The bonuses are subject to achievement of annual bonus metrics set by the Board. Upon termination of the agreement by the Company for any reason other than for cause, death or disability or by one of the Executives for good reason, the Company shall pay to the Executive his or her current salary for a period of one year.

On July 15, 2020, the Company entered into an agreement with Dr. William L. Pridgen, former Chief Executive Officer of the Company, for the payment and satisfaction of salary accrued and owed to Dr. Pridgen as of that date in the amount of \$549,046. Promptly after the closing of the Company's IPO, the Company paid the accrued salary in a combination of cash and equity. A salary advance of \$100,000 paid to Dr. Pridgen in 2014 and 2015, offset the cash portion paid the equity portion at the option of Dr. Pridgen. Prior to the pricing of the Company's IPO, the split between the equity portion paid. Prior to the pricing of the IPO, the Company issued members interest for repayment of \$336,880 of accrued salary. The remaining balance of \$212,166 less the salary advance of \$100,000 that will be paid in cash was outstanding as of December 31, 2020.

On August 22, 2020, the Company amended the President's executive employment agreement to provide for an equity bonus in the form of non-qualified stock options upon the completion of an IPO, in lieu of cash and in-kind bonuses that were provided for in the original agreement. In addition to the equity bonus, the President shall participate in the Company's executive bonus program alongside and to the same extent the other executives are awarded and paid such bonuses at a target rate of 50% of his base salary. A previously paid bonus advance of \$150,000 offset the equity bonus options granted.

The Company also owed the President accrued salary in the amount of \$466,667. The President was issued members interest for repayment of \$200,000 of accrued salary just prior to the pricing of the IPO on December 16, 2020. The remaining balance of \$266,667 that will be paid in cash was outstanding as of December 31, 2020. Upon the pricing of the Company's IPO, the President resigned and was appointed to the Company's board of directors.

On September 10, 2020, the Company entered into an employment agreement setting forth the terms of employment for the Company's Chief Medical Officer (the "CMO"), commencing fifteen days after the Company converts to a Delaware Corporation in connection with its IPO (the "Commencement Date"). Per the terms of the agreement and upon the establishment of a bonus program approved by the Board, the CMO is entitled to receive a cash bonus with a target amount of no less than 35% of his then-current base salary. In addition to the cash bonus, on the Commencement Date, the CMO will be issued options. See Note 13 for the options grant provided in 2021. The term of the agreement will continue in effect until notice is provided for termination by either party. Upon termination of the agreement by the Company for any reason other than for cause, death or disability or by the CMO for good reason, the Company shall pay the CMO 25% of his current then current annual salary plus a prorated portion of his cash bonus for the year over a period of three months and health benefits for a period of 12 months unless Dr. Gendreau becomes eligible for health benefits under another employer. In the event of termination in connection with a change in control, in lieu of the severance payment discussed above, Dr. Gendreau is entitled to receive a cash payment equal to 1.0 times his then-current annual base salary plus 1.0 times his cash bonus for the year in which the termination occurs. The Commencement Date was determined to be January 1, 2021.

Strategic Advisor Engagement

In May 2017, the Company entered into an agreement with Torrey Capital ("Torreya"), a division of the Financial West Investment Group, to engage Torreya as the Company's advisor to (1) assist in a financing transaction which would involve raising capital for the Company or (2) facilitate a strategic transaction to sale the Company or its intellectual property, merge the Company with another player, or alternatively, secure a partnership whereby a third party would agree to share development costs and/or assume commercialization rights to one of the Company's products in development. As compensation for Torreya's services, the Company agreed to pay Torreya the following:

- A cash fee of 3% of gross proceeds upon completion of a financing transaction from parties that were introduced by Torreya or where Torreya was materially involved in arranging for an investment.
- A cash fee of 3% of all payments received by the Company at the closing of a strategic transaction and 3% of any future payments received by the Company, in no case to be less than \$1 million upon the first close of the transaction.

The Company has not recognized any expense or associated liability in connection with either the financing transaction fee or the strategic transaction fee as they are not considered probable as of December 31, 2020 and 2019.

11. Share-based compensation

Equity Incentive Plan

Effective upon the closing of the Company's IPO on December 21, 2020, the Company's 2020 Equity Incentive Plan (the "Plan") became effective. Under 2020 Plan, 812,500 shares are authorized to be issued. As of December 31, 2020, 293,337 shares were available for future grants.

The Plan provides for grants to employees, members of the Board, consultants and advisors to the Company, in the form of stock awards, options, and other equity-based awards. The amount and terms of grants are determined by the Board. Stock options have a maximum term of 10 years after date of grant and are exercisable in cash or as otherwise determined by the Board. The maximum aggregate number of shares of shares during any calendar year for an individual is limited to 500,000.

As of December 31, 2020, options to purchase common shares of the Company outstanding under the Plan were as follows:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)
Outstanding at December 31, 2019	—	\$ —	—
Granted	519,163	10.00	—
Exercised	—	—	—
Forfeited	—	—	—
Outstanding at December 31, 2020	<u>519,163</u>	<u>\$ 10.00</u>	<u>9.98</u>
Exercisable at December 31, 2020	<u>519,163</u>	<u>\$ 10.00</u>	<u>9.98</u>

As of December 31, 2020 the aggregate intrinsic value of options outstanding and exercisable was \$0.

Upon the closing of the Company's IPO on December 21, 2020, the Company granted to employees, pursuant to their individual employment agreements as discussed above, 519,163 options to purchase the Company's Common Stock with an exercise price of \$10.00 per share and a term of 10 years. The options were 100% vested at the grant date. The options had an aggregate grant date fair value of \$3,441,687 that was calculated using the Black-Scholes option-pricing model. Variables used in the Black-Scholes option pricing model include: (1) discount rate of 0.39% based on the daily yield curve rates for U.S. Treasury obligations, (2) expected life of 5.0 years based on the simplified method provided in Staff Accounting

Bulletin, (3) expected volatility of 88.3% based on the average historical volatility of comparable companies' stock, (4) no expected dividends and (5) fair market value of the Company's stock of \$9.80 per share.

The Company recognized share-based compensation expense of \$3,441,687 during 2020 related to stock options. As of December 31, 2020, there was no unrecognized compensation expense related to stock options as the options were 100% vested upon issuance.

Underwriters Warrants

In conjunction with the IPO, the Company granted the underwriters 172,500 warrants to purchase shares of the Company's common stock at an exercise price of \$12.50 per share, which is 125% of the initial public offering price. The warrants have a five-year term and are not exercisable prior to December 21, 2021.

The Company has accounted for the warrants as equity-based awards issued to a non-employee. The warrants had an aggregate grant date fair value of \$1,108,785 that was calculated using the Black-Scholes option-pricing model. Variables used in the Black-Scholes option pricing model include: (1) discount rate of 0.37% based on the daily yield curve rates for U.S. Treasury obligations, (2) expected life of 5.0 years, (3) expected volatility of 88.3% based on the average historical volatility of comparable companies' stock, (4) no expected dividends and (5) fair market value of the Company's stock of \$10.00 per share.

There was no net impact recognized by the Company in the accompanying financial statements as the warrants were equity-based awards issued for services rendered by the underwriter for the IPO that was offset by the Company recognizing the fair value of the warrants as a direct and incremental costs associated with the IPO by reducing paid-in capital for the same amount. There is no unrecognized compensation expense for these awards as of December 31, 2020.

As of December 31, 2020, underwriters warrants to purchase common shares of the Company outstanding were as follows:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)
Outstanding at December 31, 2019	—	\$ —	—
Granted (1)	172,500	12.50	—
Exercised	—	—	—
Forfeited	—	—	—
Outstanding at December 31, 2020 (1)	<u>172,500</u>	<u>\$ 12.50</u>	<u>4.96</u>
Exercisable at December 31, 2020 (1)	<u>172,500</u>	<u>\$ 12.50</u>	<u>4.96</u>

(1) The warrant table above excludes the warrant feature that was included in convertible promissory notes as further outlined in Note 6 as these warrants were not considered freestanding instruments that required bifurcation.

As of December 31, 2020, the aggregate intrinsic value of warrants outstanding and exercisable was \$0.

Non-qualified Stock Options

In conjunction with the IPO and the President's executive employment agreement, the Company granted to the President 292,500 of non-qualified stock options as an equity bonus in lieu of cash and in-kind bonuses provided for in the President's original employment agreement. As part of the amended employment agreement dated August 22, 2020, the President received non-qualified stock options equal to 6.0% of the outstanding shares of the Company immediately prior to the IPO at a strike price equal to the pre-money valuation of the Company which was \$10.00 per share. A previously paid bonus advance of \$150,000 offset

the equity bonus at the time of grant. The options are exercisable within 10 years of the date of grant and were 100% vested at the grant date.

The options had an aggregate grant date fair value of \$1,987,831 that was calculated using the Black-Scholes option-pricing model. Variables used in the Black-Scholes option pricing model include: (1) discount rate of 0.37% based on the daily yield curve rates for U.S. Treasury obligations, (2) expected life of 5.0 years based on the simplified method provided in Staff Accounting Bulletin, (3) expected volatility of 88.3% based on the average historical volatility of comparable companies' stock, (4) no expected dividends and (5) fair market value of the Company's stock of \$10.00 per share. The Company recognized share-based compensation expense of \$1,987,831 during 2020 related to stock options. As of December 31, 2020, there was no unrecognized compensation expense related to these options as they were 100% vested upon issuance.

These options are for unregistered securities, and the option agreement does not include a registration rights agreement. Consequently, the Company has not recognized a contingent liability associated with registering the securities for the arrangement.

As of December 31, 2020, the unregistered options to purchase common shares of the Company outstanding were as follows:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)
Outstanding at December 31, 2019	—	\$ —	—
Granted	292,500	10.00	—
Exercised	—	—	—
Forfeited	—	—	—
Outstanding at December 31, 2020	<u>292,500</u>	<u>\$ 10.00</u>	<u>9.96</u>
Exercisable at December 31, 2020	<u>292,500</u>	<u>\$ 10.00</u>	<u>9.96</u>

As of December 31, 2020 the aggregate intrinsic value of the unregistered options outstanding and exercisable was \$0.

12. Income Taxes

Prior to the Company's Corporate Conversion, the Company operated as an Alabama limited liability company that passes through income and losses to its members. As a result, the Company was not subject to any U.S. federal or U.S. state income taxes as the related tax consequences are reported by the individual members. Upon the Corporate Conversion, the Company converted to a Delaware corporation and is now subject to filing U.S. federal and various U.S. state income tax returns. This, in conjunction with the Company's losses for the short period between the Corporate Conversion and year end, there is no income tax expense or benefit for years ended December 31, 2020 and 2019.

A reconciliation of the U.S. federal income tax rate to the Company's effective tax rate is as follows:

	Year Ended December 31, 2020
U.S. federal statutory income tax rate	21.00 %
Permanent differences	(1.56) %
State taxes, net of federal benefit	4.20 %
Other adjustments	0.27 %
Change in valuation allowance	(23.91) %
Effective Income Tax rate	— %

Deferred taxes are recognized for temporary differences between the basis of assets and liabilities for financial statement and income tax purposes. The significant components of the Company's deferred tax assets are comprised of the following:

	As of December 31,	
	2020	2019
Deferred tax assets:		
Net operating loss carryforwards	\$ 591,439	\$ —
Stock compensation	1,310,207	—
Accrual to cash adjustments	314,492	422,026
Investment in partnership	31,136	31,858
Amortization	17,467	—
Allowance for uncollectible receivable	—	5,243
Gross deferred tax assets	2,264,741	459,127
Valuation allowance	(1,836,300)	(449,222)
Net deferred tax assets	428,441	9,905
Deferred tax liabilities:		
Prepaid expenses	(428,441)	(1,498)
Debt issuance costs	—	(8,407)
Deferred tax liabilities	(428,441)	(9,905)
Net deferred taxes	\$ —	\$ —

The Company has estimated net operating loss carryforwards ("NOLs") of \$2,315,510 for both Federal income tax purposes and for Georgia income tax purposes as of December 31, 2020. These net operating losses can be carried forward and applied against future taxable income, if any. These losses currently have no expiration date and may be carried forward indefinitely. As the tax year ended December 31, 2020 is the Company's initial tax year as a C-Corporation, there are no previously filed corporate returns open under statute.

The Company has recorded a full valuation allowance against its net deferred tax assets as of December 31, 2020 and 2019 because the Company has determined that it is more likely than not that these assets will not be fully realized due to historic net operating losses incurred. The ultimate realization of the deferred tax assets is dependent upon the generation of future taxable income during the periods in which these temporary differences become deductible.

The Company experienced a net change in valuation allowance of \$1,387,078 in the year ended December 31, 2020.

On March 27, 2020, the Coronavirus Aid, Relief and Economic Security ("CARES Act") Act was enacted and signed into law. The CARES Act included a number of income tax law changes, including modifications

to the interest limitation under IRC §163(j) and reinstatement of the ability to carry back net operating losses. The income tax items in the CARES Act do not have an impact on the Company's 2020 income tax provision.

13. Subsequent Events

On January 1, 2021, the Commencement Date of the CMO's employment, the Company granted options to purchase 41,734 shares of the Company's common stock for a term of 10 years, at an exercise price equal to the fair value of the stock at the close of market of \$7.51, and a vesting period of 33.333% after one year and 66.667% in 24 monthly installments, thereafter. The options had an aggregated grant date fair value of \$228,412 that was calculated using the Black-Scholes option-pricing model. Variables used in the Black-Scholes option-pricing model include: (1) a discount rate of 0.505% based on the daily yield curve rates for U.S. Treasury obligations, (2) expected life of 6 years based on the simplified method (vesting plus contractual term divided by two), (3) expected volatility of 89.04% based on the historical volatility of comparable companies' stock, (4) no expected dividends and (5) fair market value of the Company's stock of \$7.51 per share.

In January 2021, of the outstanding 104,083 warrants related to the conversion of the promissory notes at the Company's Corporate Conversion, 25,315 warrants were exercised for \$197,561. The remaining unexercised warrants of 78,768 expired on January 20, 2021.

Subsequent to year-end, the Company entered into an employment agreement with its new Director of Clinical Operations (the "Director"), effective February 1, 2021. Per the term of the agreement and upon the establishment of a bonus program approved by the Board, the Director is entitled to receive a cash bonus of no less than 20% of the then-current base salary. The bonus is subject to achievement of annual bonus metrics set by the Board. The term of the agreement will continue in effect until notice is provided for termination by either party. If the termination of the agreement is related to a change of control, the Director is entitled to receive a change of control termination payment equal to 50% of her then current base salary and 50% of the bonus for the year in which the termination occurs.

On February 1, 2021, the Company granted options to the Director to purchase 21,000 shares of the Company's common stock for a term of 10 years, at an exercise price equal to the fair market value of the stock at the close of market of \$6.75, and a vesting period of 33.333% after one year and 66.667% in 24 monthly installments, thereafter. The options had an aggregated grant date fair value of \$104,240 that was calculated using the Black-Scholes option-pricing model. Variables used in the Black-Scholes option-pricing model include: (1) a discount rate of 0.59% based on the daily yield curve rates for U.S. Treasury obligations, (2) expected life of 6 years based on the simplified method (vesting plus contractual term divided by two), (3) expected volatility of 90.16% based on the historical volatility of comparable companies' stock, (4) no expected dividends and (5) fair market value of the Company's stock of \$6.75 per share.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures.

Our management, with the participation of our Chief Executive Officer and SVP of Finance, has evaluated the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of the end of the period covered by this Annual Report on Form 10-K. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost benefit relationship of possible controls and procedures.

Based upon that evaluation and the material weakness in our internal control over financial reporting discussed below, our Chief Executive Officer and SVP of Finance concluded that, as of the end of the period covered by this Annual Report on Form 10-K, our disclosure controls and procedures were not effective at a reasonable assurance level in ensuring that material information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the rules, regulations and forms of the SEC, including ensuring that such material information is accumulated by and communicated to our management, including our Chief Executive Officer and SVP of Finance, as appropriate to allow timely decisions regarding required disclosure.

In the preparation of our consolidated financial statements to meet the requirements of our IPO and for the period covered by this Annual Report on Form 10-K, we determined that a material weakness in our internal control over financial reporting arose because we did not maintain effective segregation of duties, financial statement reporting and general technology controls. Inability to fully segregate responsibilities can result in error and create opportunity for fraud. Similarly, the use of information technology can affect the manner in which transactions are initiated, authorized, recorded, processed, and reported. Failure to properly secure the access rights to significant applications can result in errors and/or irregularities in the course of performing day-to-day activities and enable unauthorized personnel to retrieve and modify financial statement data. Our structure and size does not enable us to fully segregate financial statement accounting and operational functions, including financial statements and critical supporting schedules. Further, we currently do not have automated technology controls that ensure proper segregation of duties exists, including but not limited to, general ledger access, vendor management, and the ability to authorize and release wire transactions and other payments.

We cannot assure you that the steps and measures we will implement to remediate our material weakness will be sufficient to prevent future material weaknesses or significant deficiencies in our internal control over financial reporting from occurring.

Management's Report on Internal Control Over Financial Reporting

This Annual Report on Form 10-K does not include a report of management's assessment regarding internal control over financial reporting or an attestation report of our independent registered public accounting firm due to a transition period established by rules of the Securities and Exchange Commission for newly public companies.

Changes in Internal Control Over Financial Reporting

There was no change in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(f) of the Exchange Act that occurred during the quarter

ended December 31, 2020 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

None.

PART III

Item 10. Directors, Executive Officers, and Corporate Governance

We incorporate the information required by this Item 10 by reference to the definitive proxy statement for our 2021 annual meeting of shareholders, to be filed with the SEC.

Item 11. Executive Compensation

We incorporate the information required by this Item 11 by reference to the definitive proxy statement for our 2021 annual meeting of shareholders, to be filed with the SEC.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

We incorporate the information required by this Item 12 by reference to the definitive proxy statement for our 2021 annual meeting of shareholders, to be filed with the SEC.

Item 13. Certain Relationships and Related Transactions, and Director Independence

We incorporate the information required by this Item 13 by reference to the definitive proxy statement for our 2021 annual meeting of shareholders, to be filed with the SEC.

Item 14. Principal Accountant's Fees and Services

We incorporate the information required by this Item 14 by reference to the definitive proxy statement for our 2021 annual meeting of shareholders, to be filed with the SEC.

Part IV

Item 15. Exhibits and Financial Statement Schedules

(a) The following documents are filed or furnished as part of this Form 10-K:

1. Financial Statements

Reference is made to the Index to Financial Statements under Item 8, Part II hereof.

2. Financial Statement Schedules

The Financial Statement Schedules have been omitted because they are not applicable, not required, or the information is shown in the financial statements or related notes.

3. Exhibits

EXHIBIT INDEX

Exhibit Number	Description
2.1	Plan of Conversion (incorporated by reference herein from Exhibit 2.1 to the Company's Registration Statement of Form S-1, filed with the SEC on August 28, 2020)
2.2	Certificate of Conversion of Virios Therapeutics, LLC (incorporated by reference herein from Exhibit 2.2 to the Company's Registration Statement of Form S-1, filed with the SEC on August 28, 2020)
3.1	Certificate of Incorporation of Virios Therapeutics, Inc. (incorporated by reference herein from Exhibit 3.1 to the Company's Registration Statement of Form S-1, filed with the SEC on August 28, 2020)
3.2	Bylaws of Virios Therapeutics, Inc. (incorporated by reference herein from Exhibit 3.2 to the Company's Registration Statement of Form S-1, filed with the SEC on August 28, 2020)
4.1	Specimen Certificate evidencing shares of the Registrant's common stock. (incorporated by reference herein from Exhibit 4.1 to the Company's Registration Statement of Form S-1, filed with the SEC on October 16, 2020)
4.2*	Description of Registrant's Securities.
10.1+	Agreement, dated June 1, 2012, by and between William L. Pridgen and Innovative Med Concepts, LLC, (incorporated by reference herein from Exhibit 10.1 to the Company's Registration Statement of Form S-1, filed with the SEC on August 28, 2020)
10.2+	Employment Agreement, dated March 3, 2015, by and between Richard Burch and Innovative Med Concepts, LLC, as amended. (incorporated by reference herein from Exhibit 10.2 to the Company's Registration Statement of Form S-1, filed with the SEC on August 28, 2020)
10.3+	Employment Agreement, dated April 5, 2020, by and between Greg Duncan and Innovative Med Concepts, LLC, as amended. (incorporated by reference herein from Exhibit 10.3 to the Company's Registration Statement of Form S-1, filed with the SEC on August 28, 2020)
10.4+	Employment Agreement, dated April 5, 2020, by and between Angela Walsh and Innovative Med Concepts, LLC, as amended. (incorporated by reference herein from Exhibit 10.4 to the Company's Registration Statement of Form S-1, filed with the SEC on August 28, 2020)
10.5+	Employment Agreement, dated April 5, 2020, by and between Ralph Grosswald and Innovative Med Concepts, LLC, as amended. (incorporated by reference herein from Exhibit 10.5 to the Company's Registration Statement of Form S-1, filed with the SEC on August 28, 2020)
10.6+	Virios Therapeutics, Inc. 2020 Equity Incentive Plan. (incorporated by reference herein from Exhibit 10.6 to the Company's Registration Statement of Form S-1, filed with the SEC on August 28, 2020)
10.7	University of Alabama Know-How License Agreement, dated June 1, 2012, by and between The Board of Trustees of The University of Alabama for and on behalf of its component institution The University of Alabama and Innovative Med Concepts, LLC. (incorporated by reference herein from Exhibit 10.7 to the Company's Registration Statement of Form S-1, filed with the SEC on August 28, 2020)
10.8+	Employment Agreement, dated September 10, 2020, by and between R. Michael Gendreau and Virios Therapeutics, LLC. (incorporated by reference herein from Exhibit 10.8 to the Company's Registration Statement of Form S-1, filed with the SEC on September 16, 2020)
10.9+	Agreement, dated July 15, 2020, by and between William L. Pridgen and Innovative Med Concepts, LLC. (incorporated by reference herein from Exhibit 10.9 to the Company's Registration Statement of Form S-1, filed with the SEC on December 1, 2020)
23.1*	Consent of Dixon Hughes Goodman LLP.
31.1*	Certification of Chief Executive Officer Pursuant to Rule 13a-15(e) or Rule 15d-15(e).*
31.2*	Certification of Chief Financial Officer Pursuant to Rule 13a-15(e) or Rule 15d-15(e).*
32*	Certification of Chief Executive Officer and Chief Financial Officer of Periodic Report Pursuant to 18 U.S.C. Section 1350.*

- * Filed with this Annual Report on Form 10-K.
- + Indicates management contract or compensatory plan.

Item 16. Form 10- K Summary

None.

DESCRIPTION OF CAPITAL STOCK

As of December 31, 2020, the common stock of Virios Therapeutics, Inc. (the “Company”) is registered under Section 12(b) of the Securities Exchange Act of 1934, as amended (the “Exchange Act”).

The following description of our capital stock, certain provisions of our certificate of incorporation and bylaws and certain provisions of Delaware law is a summary and is qualified in its entirety by reference to our certificate of incorporation, bylaws and the Delaware General Corporation Law (the “DGCL”). Copies of our certificate of incorporation and our bylaws have been filed with the SEC and are filed as exhibits to the Company’s Annual Report on Form 10-K filed with the Securities and Exchange Commission of which this Exhibit is a part.

General

Our authorized capital stock consists of 43,000,000 shares of common stock, par value \$0.0001 per share, and 2,000,000 shares of preferred stock, par value \$0.0001 per share. As of December 31, 2020, there were 8,305,075 shares of our common stock, held by approximately 205 stockholders of record and no shares of our preferred stock are designated, issued or outstanding.

Common Stock

Holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of stockholders and do not have cumulative voting rights. An election of directors by our stockholders shall be determined by a plurality of the votes cast by the stockholders entitled to vote in the election. Subject to the supermajority votes for some matters, other matters shall be decided by the affirmative vote of our stockholders having a majority in voting power of the votes cast by the stockholders present or represented and voting on such matter. Holders of common stock are entitled to receive proportionately any dividends as may be declared by our board of directors, subject to any preferential dividend rights of any series of preferred stock that we may designate and issue in the future.

In the event of our liquidation or dissolution, the holders of common stock are entitled to receive on a pro rata basis our net assets available for distribution to stockholders after the payment of all debts and other liabilities, subject to the prior rights of any holders of outstanding preferred stock. Holders of common stock have no preemptive, subscription, redemption or conversion rights. The rights, preferences and privileges of holders of common stock are subject to and may be adversely affected by the rights of the holders of shares of any series of preferred stock that we may designate and issue in the future.

Preferred Stock

Under the terms of our certificate of incorporation our board of directors is authorized to direct us to issue shares of preferred stock in one or more series without stockholder approval. Our board of directors has the discretion to determine the rights, preferences, privileges and restrictions, including voting rights, dividend rights, conversion rights, redemption privileges and liquidation preferences, of each series of preferred stock.

The purpose of authorizing our board of directors to issue preferred stock and determine its rights and preferences is to eliminate delays associated with a stockholder vote on specific issuances. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions, future financings and other corporate purposes, could have the effect of making it more difficult for a third party to acquire, or could discourage a third party from seeking to acquire, a majority of our outstanding voting stock. Upon the closing of this offering, there will be no shares of preferred stock outstanding, and we have no present plans to issue any shares of preferred stock.

Anti-Takeover Effects of Delaware Law and Our Certificate of Incorporation and Bylaws

Some provisions of Delaware law, our certificate of incorporation and our bylaws make the following transactions more difficult: an acquisition of us by means of a tender offer; an acquisition of us by means of a proxy contest or otherwise; or the removal of our incumbent officers and directors. It is possible that these provisions could make it more difficult to accomplish or could deter transactions that stockholders may otherwise consider to be in their best interest or in our best interests, including transactions which provide for payment of a premium over the market price for our shares.

These provisions, summarized below, are intended to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to encourage persons seeking to acquire control of us to first negotiate with our board of directors. We believe that the benefits of the increased protection of our potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure us outweigh the disadvantages of discouraging these proposals because negotiation of these proposals could result in an improvement of their terms.

Authorized but Unissued Shares

Our authorized but unissued shares of common stock and preferred stock are available for future issuance without stockholder approval. These additional shares may be utilized for a variety of corporate purposes, including future public offerings to raise additional capital and corporate acquisitions. The existence of authorized but unissued shares of common stock and preferred stock could render more difficult or discourage an attempt to obtain control of a majority of our common stock by means of a proxy contest, tender offer, merger or otherwise.

Stockholder Meetings

Any action to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and not be taken by written consent.

Requirements for Advance Notification of Stockholder Nominations and Proposals

Stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide advance notice in writing, and also specify requirements as to the form and content of a stockholder's notice.

Delaware Anti-Takeover Statute

We are subject to Section 203 of the General Corporation Law of the State of Delaware, which prohibits persons deemed to be "interested stockholders" from engaging in a "business combination" with a publicly held Delaware corporation for three years following the date these persons become interested stockholders unless the business combination is, or the transaction in which the person became an interested stockholder was, approved in a prescribed manner or another prescribed exception applies. Generally, an "interested stockholder" is a person who, together with affiliates and associates, owns, or within three years prior to the determination of interested stockholder status did own, 15% or more of a corporation's voting stock. Generally, a "business combination" includes a merger, asset or stock sale, or other transaction resulting in a financial benefit to the interested stockholder. The existence of this provision may have an anti-takeover effect with respect to transactions not approved in advance by the board of directors.

Choice of Forum

The Court of Chancery of the State of Delaware is the exclusive forum in which we and our directors may be sued by our stockholders, to the fullest extent permitted by law, 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 Delaware General Corporation Law, our certificate of incorporation, or our bylaws; or
- any action asserting a claim against us that is governed by the internal affairs doctrine.

Our bylaws will not apply to suits brought to enforce a duty or liability created by the Securities Act or the Exchange Act, or any other claim for which federal courts have exclusive jurisdiction.

These choice of forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or any of our directors, officers, or other employees, which may discourage lawsuits with respect to such claims. Alternatively, if a court were to find either choice of forum provision contained in our bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, results of operations, and financial condition.

Advance Notice Requirements

Our bylaws establish an advance notice procedure for stockholder proposals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to the board of directors. Stockholders at an annual meeting will only be able to consider proposals or nominations specified in the notice of meeting or brought before the meeting by or at the direction of the board of directors or by a stockholder who was a stockholder of record on the record date for the meeting, who is entitled to vote at the meeting and who has given our Secretary timely written notice, in proper form, of the stockholder's intention to bring that business before the meeting. Although our bylaws do not give the board of directors the power to approve or disapprove stockholder nominations of candidates or proposals regarding other business to be conducted at a special or annual meeting, our bylaws may have the effect of precluding the conduct of certain business at a meeting if the proper procedures are not followed or may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect its own slate of directors or otherwise attempting to obtain control of us.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Broadridge Corporate Issuer Solutions, Inc.

National Securities Exchange Listing

Our common stock is listed on the Nasdaq Capital Market under the symbol "VIRI."

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the registration statements (Nos. 333-248447 and 333-251544) on Forms S-1 and S-8 of Virios Therapeutics, Inc. of our report dated March 23, 2021, with respect to the financial statements of Virios Therapeutics, Inc., which appear in this 2020 Annual Report on Form 10-K.

/s/ Dixon Hughes Goodman LLP

Atlanta, GA
March 23, 2021

CERTIFICATIONS

I, Greg Duncan, certify that:

1. I have reviewed this annual report on Form 10-K of Virios Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements and other financial information included in this report, fairly present, in all material respects, the financial condition, results of operations, and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) (Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313);
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's Board of Directors:
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize, and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 23, 2021

/s/Greg Duncan

Greg Duncan
Chairman of the Board of Directors,
and Chief Executive Officer

CERTIFICATIONS

I, Angela Walsh, certify that:

1. I have reviewed this annual report on Form 10-K of Virios Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements and other financial information included in this report, fairly present, in all material respects, the financial condition, results of operations, and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) (Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313);
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's Board of Directors:
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize, and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 23, 2021

/s/Angela Walsh

Angela Walsh
SVP of Finance and Corporate Secretary
(Principal Financial Officer)

**STATEMENT PURSUANT TO
18 U.S.C. SECTION 1350
AS REQUIRED BY
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report of Virios Therapeutics, Inc. (the "Company") on Form 10-K for the period ending December 31, 2020, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned hereby certify that to the best of our knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934;
and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

March 23, 2021	<u>/s/ Greg Duncan</u> Greg Duncan	Chief Executive Officer and Chairman of the Board (Principal Executive Officer)
March 23, 2021	<u>/s/ Angela Walsh</u> Angela Walsh	Senior Vice President of Finance and Secretary (Principal Financial Officer)

A signed original of this written statement required by Section 906 has been provided to Virios Therapeutics, Inc. and will be retained by Virios Therapeutics, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

WRITTEN STATEMENT OF CHIEF EXECUTIVE OFFICER
AND CHIEF FINANCIAL OFFICER

Each of the undersigned, the Chairman of the Board and Chief Executive Officer and Chief Operating Officer, Chief Financial Officer, and Corporate Secretary of Virios Therapeutics, Inc. (the Company), hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to his knowledge, the Company's Annual Report on Form 10-K for the year ended December 31, 2020, as filed with the Securities and Exchange Commission on the date hereof (the Report), fully complies with the requirements of Section 13(a) or 15 (d) of the Securities Exchange Act of 1934 and that information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: March 23, 2021

/s/ Greg Duncan

Name

Chairman of the Board and Chief Executive Officer

/s/ Angela Walsh

Name

Chief Financial Officer and Corporate Secretary
